

US3252553 (Prod: Centex Studies Inc)

Generated By: KC Joubran

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US3252553

Form: Participant Creation

Data signed: (b) (4) 05 Mar 2021 22:11:58

Generated On: 09 Jun 2021 16:15:52

[Participant ID](#)

US3252553

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

US3252553

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 03:18:20

Generated On: 09 Jun 2021 16:15:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 05 Mar 2021 03:18:19

Generated On: 09 Jun 2021 16:15:52

Date of Birth (MMM yyyy)	(b) (6) 1946
Age	74
Age Units	YEARS
Age (Derived)	74
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) 05 Mar 2021 03:18:19

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Date of Informed Consent (<i>dd MMM yyyy</i>)	24 SEP 2020
Month and Year of Informed Consent (derived)	SEP 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) 05 Mar 2021 03:18:19

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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) 05 Mar 2021 03:18:19

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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) 05 Mar 2021 03:18:19

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Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 05 Mar 2021 03:18:19

Generated On: 09 Jun 2021 16:15:52

Condition	PACEMAKER
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 05 Mar 2021 03:18:19

Generated On: 09 Jun 2021 16:15:52

Condition	BRADYCARDIA
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 03:18:20

Generated On: 09 Jun 2021 16:15:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	24 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	15:36 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 15:36
Height (<i>xxx.x</i>)	75 in
Weight (<i>xxx.x</i>)	285.8 lb
BMI (<i>xxx.x</i>)	35.79724 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 03:18:20

Generated On: 09 Jun 2021 16:15:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 SEP 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) 05 Mar 2021 03:18:20

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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

SECURITY GUARD

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) 05 Mar 2021 03:18:20

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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) 05 Mar 2021 03:18:20

Generated On: 09 Jun 2021 16:15:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 05 Mar 2021 03:18:20

Generated On: 09 Jun 2021 16:15:52

What was the date of randomization? (dd MMM yyyy) 24 SEP 2020

What was the participant's randomization number? 191363

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) 05 Mar 2021 03:18:20

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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) 05 Mar 2021 03:18:20

Generated On: 09 Jun 2021 16:15:52

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)	24 SEP 2020
Time of assessment (00:00-23:59)	15:36 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 15:36
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 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) 05 Mar 2021 03:18:20

Generated On: 09 Jun 2021 16:15:52

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	24 SEP 2020
Time of assessment (00:00-23:59)	16:36 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 16:36
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 03:18:20

Generated On: 09 Jun 2021 16:15:52

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 03:18:20

Generated On: 09 Jun 2021 16:15:52

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) 24 SEP 2020

What was the treatment time? (00:00-23:59) 16:06 (24 HR)

Treatment Date and Time (derived) 24 SEP 2020 16:06

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 03:18:20

Generated On: 09 Jun 2021 16:15:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 SEP 2020
Collection time (00:00-23:59)	15:47 (24 HR)
Collection date and time (derived)	24 SEP 2020 15:47

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 03:18:20

Generated On: 09 Jun 2021 16:15:52

Collection date (dd MMM yyyy)			24 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:44	24 SEP 2020 15:44
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 03:18:20

Generated On: 09 Jun 2021 16:15:52

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: 09 Jun 2021 16:15:52

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 16:38

PC Open Date & Time

24 SEP 2020 16:26

PC Close Date & Time

24 SEP 2020 18:56

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

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

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 24 SEP 2020 19:51

PC Close Date & Time 25 SEP 2020 11:59

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:15:52

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 ☒

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 SEP 2020 13:55

PC Open Date & Time 25 SEP 2020 12:00

PC Close Date & Time 26 SEP 2020 11:59

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 16:27

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 21:05

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °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

29 SEP 2020 14:12

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:15:52

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

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 14:46

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 16:39

PC Open Date & Time

24 SEP 2020 16:26

PC Close Date & Time

24 SEP 2020 18:56

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

24 SEP 2020 19:51

PC Close Date & Time

25 SEP 2020 11:59

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:15:52

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

25 SEP 2020 13:59

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:15:52

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

26 SEP 2020 16:30

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:15:52

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

27 SEP 2020 21:06

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:15:52

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

29 SEP 2020 14:15

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:15:52

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

30 SEP 2020 14:47

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

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 ☐

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 16:40
PC Open Date & Time	24 SEP 2020 16:26
PC Close Date & Time	24 SEP 2020 18:56

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Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

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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 ☐

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

24 SEP 2020 19:51

PC Close Date & Time

25 SEP 2020 11:59

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

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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Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 14:47
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

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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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

Yes ☐

PC Time stamp

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 21:08
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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Yes ☐

PC Time stamp

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

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 ☐

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Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

Yes ☐

PC Time stamp

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

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)

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Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

Yes ☐

PC Time stamp

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 8

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 ☐

PC Time Stamp 01 OCT 2020 18:57

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

US3252553

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	01 OCT 2020 18:57
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3252553

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 8

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 01 OCT 2020 18:58

PC Open Date and Time 01 OCT 2020 12:00

PC Close Date and Time 02 OCT 2020 11:59

US3252553

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 03:18:19

Generated On: 09 Jun 2021 16:15:52

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 1 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3252553

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 03:18:19

Generated On: 09 Jun 2021 16:15:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252553

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 03:18:19

Generated On: 09 Jun 2021 16:15:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252553

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 03:18:19

Generated On: 09 Jun 2021 16:15:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252553

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 03:18:19

Generated On: 09 Jun 2021 16:15:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252553

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 03:18:19

Generated On: 09 Jun 2021 16:15:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252553

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 03:18:20

Generated On: 09 Jun 2021 16:15:52

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy) _____

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

Folder OID VISIT2

US3252553

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 03:18:20

Generated On: 09 Jun 2021 16:15:52

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

US3252553

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 03:18:20

Generated On: 09 Jun 2021 16:15:52

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
Date of assessment (<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	

US3252553

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 03:18:20

Generated On: 09 Jun 2021 16:15:52

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.

US3252553

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 03:18:20

Generated On: 09 Jun 2021 16:15:52

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 VISIT IS SCHEDULED

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? _____

US3252553

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 03:18:20

Generated On: 09 Jun 2021 16:15:52

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3252553

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 03:18:20

Generated On: 09 Jun 2021 16:15:52

Collection date (*dd MMM yyyy*)

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

US3252553

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 03:18:20

Generated On: 09 Jun 2021 16:15:52

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

21 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2020 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

28 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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 <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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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 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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

10 APR 2021 01:41:54

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

25 APR 2021 00:16:23

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

01 MAY 2021 00:28:08

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

08 MAY 2021 00:01

Patient Cloud Close Date & Time

12 MAY 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

15 MAY 2021 00:01

Patient Cloud Close Date & Time

19 MAY 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

22 MAY 2021 00:01

Patient Cloud Close Date & Time

26 MAY 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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 <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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

29 MAY 2021 00:01

Patient Cloud Close Date & Time

02 JUN 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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 <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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

05 JUN 2021 00:01

Patient Cloud Close Date & Time

09 JUN 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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="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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

12 JUN 2021 00:01

Patient Cloud Close Date & Time

16 JUN 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 JUN 2021 00:01

Patient Cloud Close Date & Time

23 JUN 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

26 JUN 2021 00:01

Patient Cloud Close Date & Time

30 JUN 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

03 JUL 2021 00:01

Patient Cloud Close Date & Time

07 JUL 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

10 JUL 2021 00:01

Patient Cloud Close Date & Time

14 JUL 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 JUL 2021 00:01

Patient Cloud Close Date & Time

21 JUL 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

24 JUL 2021 00:01

Patient Cloud Close Date & Time

28 JUL 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

31 JUL 2021 00:01

Patient Cloud Close Date & Time

04 AUG 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

07 AUG 2021 00:01

Patient Cloud Close Date & Time

11 AUG 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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="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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

14 AUG 2021 00:01

Patient Cloud Close Date & Time

18 AUG 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

21 AUG 2021 00:01

Patient Cloud Close Date & Time

25 AUG 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

28 AUG 2021 00:01

Patient Cloud Close Date & Time

01 SEP 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

04 SEP 2021 00:01

Patient Cloud Close Date & Time

08 SEP 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

11 SEP 2021 00:01

Patient Cloud Close Date & Time

15 SEP 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 SEP 2021 00:01

Patient Cloud Close Date & Time

22 SEP 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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="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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

25 SEP 2021 00:01

Patient Cloud Close Date & Time

29 SEP 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

02 OCT 2021 00:01

Patient Cloud Close Date & Time

06 OCT 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

09 OCT 2021 00:01

Patient Cloud Close Date & Time

13 OCT 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

16 OCT 2021 00:01

Patient Cloud Close Date & Time

20 OCT 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

23 OCT 2021 00:01

Patient Cloud Close Date & Time

27 OCT 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 OCT 2021 00:01

Patient Cloud Close Date & Time

03 NOV 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 NOV 2021 00:01

Patient Cloud Close Date & Time

10 NOV 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 NOV 2021 00:01

Patient Cloud Close Date & Time

17 NOV 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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="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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 NOV 2021 00:01

Patient Cloud Close Date & Time

24 NOV 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 NOV 2021 00:01

Patient Cloud Close Date & Time

01 DEC 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 DEC 2021 00:01

Patient Cloud Close Date & Time

08 DEC 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 DEC 2021 00:01

Patient Cloud Close Date & Time

15 DEC 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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="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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 DEC 2021 00:01

Patient Cloud Close Date & Time

22 DEC 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 DEC 2021 00:01

Patient Cloud Close Date & Time

29 DEC 2021 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 JAN 2022 00:01

Patient Cloud Close Date & Time

05 JAN 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 JAN 2022 00:01

Patient Cloud Close Date & Time

12 JAN 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 JAN 2022 00:01

Patient Cloud Close Date & Time

19 JAN 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 JAN 2022 00:01

Patient Cloud Close Date & Time

26 JAN 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 JAN 2022 00:01

Patient Cloud Close Date & Time

02 FEB 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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="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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 FEB 2022 00:01

Patient Cloud Close Date & Time

09 FEB 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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="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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 FEB 2022 00:01

Patient Cloud Close Date & Time

16 FEB 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 FEB 2022 00:01

Patient Cloud Close Date & Time

23 FEB 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 FEB 2022 00:01

Patient Cloud Close Date & Time

02 MAR 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 MAR 2022 00:01

Patient Cloud Close Date & Time

09 MAR 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 MAR 2022 00:01

Patient Cloud Close Date & Time

16 MAR 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 MAR 2022 00:01

Patient Cloud Close Date & Time

23 MAR 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 MAR 2022 00:01

Patient Cloud Close Date & Time

30 MAR 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 APR 2022 00:01

Patient Cloud Close Date & Time

06 APR 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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="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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 APR 2022 00:01

Patient Cloud Close Date & Time

13 APR 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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="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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 APR 2022 00:01

Patient Cloud Close Date & Time

20 APR 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 579
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 APR 2022 00:01

Patient Cloud Close Date & Time

27 APR 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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="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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

30 APR 2022 00:01

Patient Cloud Close Date & Time

04 MAY 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 593
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

07 MAY 2022 00:01

Patient Cloud Close Date & Time

11 MAY 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

14 MAY 2022 00:01

Patient Cloud Close Date & Time

18 MAY 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 MAY 2022 00:01

Patient Cloud Close Date & Time

25 MAY 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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°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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 MAY 2022 00:01

Patient Cloud Close Date & Time

01 JUN 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 JUN 2022 00:01

Patient Cloud Close Date & Time

08 JUN 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

11 JUN 2022 00:01

Patient Cloud Close Date & Time

15 JUN 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 JUN 2022 00:01

Patient Cloud Close Date & Time

22 JUN 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

25 JUN 2022 00:01

Patient Cloud Close Date & Time

29 JUN 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 JUL 2022 00:01

Patient Cloud Close Date & Time

06 JUL 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 JUL 2022 00:01

Patient Cloud Close Date & Time

13 JUL 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 663
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

16 JUL 2022 00:01

Patient Cloud Close Date & Time

20 JUL 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 JUL 2022 00:01

Patient Cloud Close Date & Time

27 JUL 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

30 JUL 2022 00:01

Patient Cloud Close Date & Time

03 AUG 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

06 AUG 2022 00:01

Patient Cloud Close Date & Time

10 AUG 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 AUG 2022 00:01

Patient Cloud Close Date & Time

17 AUG 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 AUG 2022 00:01

Patient Cloud Close Date & Time

24 AUG 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 AUG 2022 00:01

Patient Cloud Close Date & Time

31 AUG 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 SEP 2022 00:01

Patient Cloud Close Date & Time

07 SEP 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

10 SEP 2022 00:01

Patient Cloud Close Date & Time

14 SEP 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 SEP 2022 00:01

Patient Cloud Close Date & Time

21 SEP 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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="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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 SEP 2022 00:01

Patient Cloud Close Date & Time

28 SEP 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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="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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

01 OCT 2022 00:01

Patient Cloud Close Date & Time

05 OCT 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

08 OCT 2022 00:01

Patient Cloud Close Date & Time

12 OCT 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 OCT 2022 00:01

Patient Cloud Close Date & Time

19 OCT 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 OCT 2022 00:01

Patient Cloud Close Date & Time

26 OCT 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 OCT 2022 00:01

Patient Cloud Close Date & Time

02 NOV 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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="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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 NOV 2022 00:01

Patient Cloud Close Date & Time

09 NOV 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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="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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 NOV 2022 00:01

Patient Cloud Close Date & Time

16 NOV 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 2022 00:01

Patient Cloud Close Date & Time

23 NOV 2022 23:59

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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"/>

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

Patient Cloud Open Date & Time

26 NOV 2022 00:01

Patient Cloud Close Date & Time

30 NOV 2022 23:59

US3252553

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:15:52

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		13 APR 2021 15:17:53

US3252553

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:15:52

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

US3252553

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:15:52

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3252553

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

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 20:56:24

Generated On: 09 Jun 2021 16:15:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 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	UNBLND_DECIDE

US3252553

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

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 20:56:24

Generated On: 09 Jun 2021 16:15:52

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

US3252553

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Apr 2021 20:56:24

Generated On: 09 Jun 2021 16:15:52

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

US3252553

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 20:56:24

Generated On: 09 Jun 2021 16:15:52

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)	5 MAR 2021
Time of assessment (00:00-23:59)	15:37 (24 HR)
Vital Signs Date and Time (derived)	5 MAR 2021 15:37
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3252553

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 20:56:24

Generated On: 09 Jun 2021 16:15:52

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)	5 MAR 2021
Time of assessment (00:00-23:59)	16:58 (24 HR)
Vital Signs Date and Time (derived)	5 MAR 2021 16:58
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3252553

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

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 20:56:24

Generated On: 09 Jun 2021 16:15:52

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.

US3252553

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

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 20:56:24

Generated On: 09 Jun 2021 16:15:52

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) 5 MAR 2021

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

Treatment Date and Time (derived) 5 MAR 2021 16:24

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

US3252553

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 20:56:24

Generated On: 09 Jun 2021 16:15:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 MAR 2021
Collection time (00:00-23:59)	16:00 (24 HR)
Collection date and time (derived)	5 MAR 2021 16:00

US3252553

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Apr 2021 20:56:24

Generated On: 09 Jun 2021 16:15:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 MAR 2021
Collection time (00:00 - 23:59)	16:00
Collection Date and Time (derived)	5 MAR 2021 16:00

US3252553

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

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 20:56:24

Generated On: 09 Jun 2021 16:15:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252553

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 20:56:25

Generated On: 09 Jun 2021 16:15:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252553

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 20:56:25

Generated On: 09 Jun 2021 16:15:52

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

US3252553

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 02:06:20

Generated On: 09 Jun 2021 16:15:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3252553

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Apr 2021 02:06:20

Generated On: 09 Jun 2021 16:15:52

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)	6 APR 2021
Time of assessment (00:00-23:59)	09:07 (24 HR)
Vital Signs Date and Time (derived)	6 APR 2021 09:07
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3252553

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Apr 2021 02:06:20

Generated On: 09 Jun 2021 16:15:52

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)	6 APR 2021
Time of assessment (00:00-23:59)	10:18 (24 HR)
Vital Signs Date and Time (derived)	6 APR 2021 10:18
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3252553

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 02:06:20

Generated On: 09 Jun 2021 16:15:52

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.

US3252553

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 08 Apr 2021 02:06:20

Generated On: 09 Jun 2021 16:15:52

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) 6 APR 2021

What was the treatment time? (00:00-23:59) 09:41 (24 HR)

Treatment Date and Time (derived) 6 APR 2021 09:41

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

US3252553

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 02:06:20

Generated On: 09 Jun 2021 16:15:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252553

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252553

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3252553

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Mar 2021 22:11:58

Generated On: 09 Jun 2021 16:15:52

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3252553

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 11:49:36

Generated On: 09 Jun 2021 16:15:52

AEID

Adverse event

NONDISPLACED FRACTURE OF
THE LATERAL MALLEOLUS

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)

13 OCT 2020

Start time (00:00-23:59)

00:00 (24 HR)

AE start date and time (derived)

13 OCT 2020 00:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

5 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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EAB) (1725)

US3252553

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 11:49:36

Generated On: 09 Jun 2021 16:15:52

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 type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3252553

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 11:49:36

Generated On: 09 Jun 2021 16:15:52

PARTICIPANTS WIFE CALLED
IN TODAY, 24-OCT-2020,
NOTIFYING US THAT HER
HUSBAND HAS BEEN
HOSPITALIZED FOR A
FRACTURE AND
DEHYDRATION. IT IS UNSURE
AT THIS TIME IF IT IS THE
SAME FRACTURE FROM THE
PREVIOUS AE THAT WAS
REPORTED ON 13-OCT-2020.
DETAILS WILL BE UPDATED
ONCE MEDICAL RECORDS ARE
OBTAINED.

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)	

US3252553

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 11:49:36

Generated On: 09 Jun 2021 16:15:52

AEID

Adverse event

NONDISPLACED FRACTURE OF
THE RIGHT SCAPHOID

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)

13 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

5 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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EAB) (1725)

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US3252553

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 11:49:36

Generated On: 09 Jun 2021 16:15:52

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

US3252553

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 11:49:36

Generated On: 09 Jun 2021 16:15:52

AEID	USA-US108-2020-MRNA-1273-P30 1000011
Adverse event	ACUTE CHOLECYSTITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	23 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	4 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	23 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	4 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 11:49:36

Generated On: 09 Jun 2021 16:15:52

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 11:49:36

Generated On: 09 Jun 2021 16:15:52

WHILE OBTAINING MEDICAL
RECORDS FOR THE OTHER
AE'S, FRACTURES, IT WAS SEEN
THAT PATIENT WAS SEEN FOR
CHOLECYSTITIS AND WAS
HOSPITALIZED FOR THIS.
MEDICAL RECORDS FOR THIS
SAE ARE PENDING AND WILL
BE UPDATED WITH DATES AND
MEDICATIONS ONCE ARE
AVAILABLE.

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 11:49:36

Generated On: 09 Jun 2021 16:15:52

AEID	USA-US108-2020-MRNA-1273-P30 1000011
Adverse event	SEPTIC SHOCK
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	23 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	4 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	23 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	4 NOV 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 11:49:36

Generated On: 09 Jun 2021 16:15:52

Number of Days in ICU	12
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	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 11:49:36

Generated On: 09 Jun 2021 16:15:52

THE ADVERSE EVENT STARTED
AND HOSPITALIZED ON 23 OCT
2020 AND ENDED ON 04 NOV
2020. PI FOUND THIS IS AS SAE.
THE SUBJECT SHIFTED TO ICU
ON 24 OCT 2020 AND
DISCHARGED ON 04 NOV 2020.
ACCORDING TO PI, THE
INTENSITY WAS
SEVERE/GRADE 3, THE
RELATIONSHIP TO
INVESTIGATIONAL PRODUCT IS
NOT RELATED AND NO ACTION
TAKEN.

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 11:49:36

Generated On: 09 Jun 2021 16:15:52

AEID

Adverse event

CHOLELITHIASIS

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)

23 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

04 NOV 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 (6)

Data signed: (b) (4) 28 Apr 2021 11:49:36

Generated On: 09 Jun 2021 16:15:52

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input checked="" type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	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:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 11:49:36

Generated On: 09 Jun 2021 16:15:52

AEID

Adverse event

ESCHERICHIA COLI
BACTERMIA

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)

23 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

04 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 11:49:36

Generated On: 09 Jun 2021 16:15:52

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)	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 28 Apr 2021 11:49:36

Generated On: 09 Jun 2021 16:15:52

AEID

Adverse event

ACUTE GANRENOUS
CHOLECYSTITIS

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)

23 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

04 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 28 Apr 2021 11:49:36

Generated On: 09 Jun 2021 16:15:52

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)	

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 28 Apr 2021 11:49:36

Generated On: 09 Jun 2021 16:15:52

AEID

Adverse event

ENTEROCOCCUS FAECALIS
URINARY TRACT INFECTION

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)

23 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

04 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 28 Apr 2021 11:49:36

Generated On: 09 Jun 2021 16:15:52

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)	

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 28 Apr 2021 11:49:36

Generated On: 09 Jun 2021 16:15:52

AEID

Adverse event

BILIARY LEAK STATUS POST
STENT PLACEMENT

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)

23 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

04 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 28 Apr 2021 11:49:36

Generated On: 09 Jun 2021 16:15:52

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)	

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Mar 2021 22:11:58

Generated On: 09 Jun 2021 16:15:52

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 02:06:20

Generated On: 09 Jun 2021 16:15:52

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 02:06:20

Generated On: 09 Jun 2021 16:15:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 02:06:20

Generated On: 09 Jun 2021 16:15:52

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 02:06:20

Generated On: 09 Jun 2021 16:15:52

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 02:06:20

Generated On: 09 Jun 2021 16:15:52

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR
CARDIOVASCULAR DISEASE

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 02:06:20

Generated On: 09 Jun 2021 16:15:52

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 02:06:20

Generated On: 09 Jun 2021 16:15:52

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 02:06:20

Generated On: 09 Jun 2021 16:15:52

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

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 02:06:20

Generated On: 09 Jun 2021 16:15:52

Name of Medication CEPHALEXIN

Prophylaxis Yes ☐
No ☒

Indication NONDISPLACED FRACTURE OF
THE RIGHT SCAPHOID

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 02:06:20

Generated On: 09 Jun 2021 16:15:52

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	13 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	23 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 02:06:20

Generated On: 09 Jun 2021 16:15:52

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication NONDISPLACED FRACTURE OF
THE RIGHT SCAPHOID

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 02:06:20

Generated On: 09 Jun 2021 16:15:52

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 02:06:20

Generated On: 09 Jun 2021 16:15:52

Name of Medication ZOSYN

Prophylaxis Yes ☐
No ☒

Indication ACUTE CHOLECYSTITIS AND SEPSIS

Dose per administration 3.3

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 02:06:20

Generated On: 09 Jun 2021 16:15:52

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	23 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	04 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Apr 2021 20:43:22

Generated On: 09 Jun 2021 16:15:52

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 22 Apr 2021 19:06:24

Generated On: 09 Jun 2021 16:15:52

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
14 OCT 2020	X-RAYS OF RIGHT WRIST, RIGHT KNEE, AND RIGHT ANKLE	Adverse Event	
19 OCT 2020	X-RAYS OF RIGHT WRIST, RIGHT KNEE, AND RIGHT ANKLE	Adverse Event	
13 NOV 2020	X-RAYS OF RIGHT WRIST AND RIGHT ANKLE	Adverse Event	
25 NOV 2020	X-RAYS OF RIGHT ANKLE	Adverse Event	
16 DEC 2020	X-RAYS OF RIGHT WRIST AND RIGHT ANKLE	Adverse Event	
13 JAN 2021	X-RAYS OF RIGHT WRIST AND RIGHT ANKLE	Adverse Event	
23 OCT 2020	LAPAROSCOPIC CONVERTED TO OPEN SUBTOTAL CHOLECYSTECTOMY	Adverse Event	
25 OCT 2020	EXPLORATORY LAPAROTOMY	Adverse Event	
29 OCT 2020	MIDLINE PLACEMENT	Adverse Event	
25 OCT 2020	PARTIAL CHOLECYSTECTOMY (POSTERIOR WALL)	Adverse Event	
25 OCT 2020	CONTROL OF CYSTIC DUCT WITH CLIPS	Adverse Event	
25 OCT 2020	ABDOMINAL LAVAGE	Adverse Event	
25 OCT 2020	FASCIAL CLOSURE	Adverse Event	

US3252553

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 05 Apr 2021 20:43:22

Generated On: 09 Jun 2021 16:15:52

Date of dosing discontinuation (dd MMM yyyy) 01 DEC 2020

Primary reason for dosing discontinuation

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

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify PATIENT DISCONTINUED DUE TO AE# 9,8,7,6,5,4

US3252553

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 05 Apr 2021 20:43:22

Generated On: 09 Jun 2021 16:15:52

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 ☐

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 22 Apr 2021 19:06:25

Generated On: 09 Jun 2021 16:15:52

SAEID	USA-US108-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 22 Apr 2021 19:06:25

Generated On: 09 Jun 2021 16:15:52

SAEID	USA-US108-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	28/OCT/2020 17:01
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

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Data signed: (b) (4) 22 Apr 2021 19:06:25

Generated On: 09 Jun 2021 16:15:52

SAEID	USA-US108-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	25/NOV/2020 12:45
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

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Data signed: (b) (4) 22 Apr 2021 19:06:25

Generated On: 09 Jun 2021 16:15:52

SAEID	USA-US108-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	18/FEB/2021 15:03
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (4)

Data signed: (b) (4) 22 Apr 2021 19:06:25

Generated On: 09 Jun 2021 16:15:52

SAEID	USA-US108-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	26/FEB/2021 10:41
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

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (5)

Data signed: (b) (4) 22 Apr 2021 19:06:25

Generated On: 09 Jun 2021 16:15:52

SAEID	USA-US108-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	12/MAR/2021 11:25
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (6)

Data signed: (b) (4) 22 Apr 2021 19:06:25

Generated On: 09 Jun 2021 16:15:52

SAEID	USA-US108-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	15/MAR/2021 08:37
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

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (7)

Data signed: (b) (4) 22 Apr 2021 19:06:25

Generated On: 09 Jun 2021 16:15:52

SAEID	USA-US108-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	19/MAR/2021 10:23
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (8)

Data signed: (b) (4) 22 Apr 2021 19:06:25

Generated On: 09 Jun 2021 16:15:52

SAEID	USA-US108-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	24/MAR/2021 13:26
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

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (9)

Data signed: (b) (4) 22 Apr 2021 19:06:25

Generated On: 09 Jun 2021 16:15:52

SAEID	USA-US108-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	24/MAR/2021 13:35
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.	True

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (10)

Data signed: (b) (4) 22 Apr 2021 19:06:25

Generated On: 09 Jun 2021 16:15:52

SAEID	USA-US108-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	31/MAR/2021 10:35
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.	True

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (11)

Data signed: (b) (4) 22 Apr 2021 19:06:25

Generated On: 09 Jun 2021 16:15:52

SAEID	USA-US108-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	07/APR/2021 13:34
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

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (12)

Data signed: (b) (4) 22 Apr 2021 19:06:25

Generated On: 09 Jun 2021 16:15:52

SAEID	USA-US108-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	15/APR/2021 14:11
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

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (13)

Data signed: (b) (4) 22 Apr 2021 19:06:25

Generated On: 09 Jun 2021 16:15:52

SAEID	USA-US108-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	22/APR/2021 13:55
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

US3252553 (Prod: Centex Studies Inc)

US3252553

Form: Participant Creation

Generated On: 09 Jun 2021 16:15:52

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
User entered 'US3252553'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 20:39:16

US3252553

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 21:41:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Sep 2020 21:41:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:41:32
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 21:13:47
User entered empty.	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:13:47

US3252553

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '24 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 20:39:17

US3252553

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'Clinic (Clinic)' reason for change:	Joanna Gurrola Mahoney	24 Sep 2020 21:41:32
Data Entry Error	(b) (4)	
User entered empty.	Joanna Gurrola Mahoney	24 Sep 2020 21:13:47
	(b) (4)	

US3252553

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered 'SCRN'	System	24 Sep 2020 21:41:32
User entered empty.	System	24 Sep 2020 21:13:47

US3252553

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:52

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered (b) (6) 1946'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 20:39:19

US3252553

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:52

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '74'	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:42:04

US3252553

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:52

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered 'YEARS'	System	24 Sep 2020 21:42:04

US3252553

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:52

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered '74'	System	24 Sep 2020 21:32:54

US3252553

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:52

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'Male (M)'	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:42:04

US3252553

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:52

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:42:04

US3252553

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:52

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'I'	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:42:04

US3252553

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:52

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '0'	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:42:04

US3252553

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:52

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '0'	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:42:04

US3252553

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:52

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '0'	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:42:04

US3252553

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:52

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '0'	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:42:04

US3252553

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:52

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '0'	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:42:04

US3252553

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:52

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:42:04

US3252553

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:52

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '0'	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:42:04

US3252553

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:52

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '0'	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:42:04

US3252553

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:15:52

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '24 Sep 2020'	Xavier Morales (b) (4)	24 Sep 2020 21:32:54
	(b) (4)	

US3252553

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered 'Sep 2020'	System	24 Sep 2020 21:32:54

US3252553

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered '2020'	System	24 Sep 2020 21:32:54

US3252553

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:15:52

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'Amendment 2 (2)'	Xavier Morales (b) (4)	24 Sep 2020 21:32:54
	(b) (4)	

US3252553

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'Yes (Y)'	Xavier Morales (b) (4)	24 Sep 2020 21:32:54
	(b) (4)	

US3252553

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:15:52

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	Xavier Morales (b) (4)	24 Sep 2020 21:32:54
	(b) (4)	

US3252553

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:15:52

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	Xavier Morales (b) (4)	24 Sep 2020 21:32:54
	(b) (4)	

US3252553

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:15:52

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'No (N)'	Xavier Morales (b) (4)	24 Sep 2020 21:32:54
	(b) (4)	

US3252553

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:15:52

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 20:39:17

US3252553

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:15:52

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered 'I'	System	24 Sep 2020 21:32:54

US3252553

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:14:12

US3252553

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:15:52

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	25 Sep 2020 07:43:18
	(b) (4)	

US3252553

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:15:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 07:44:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 07:44:46
Data point term sent to Coder	System	25 Sep 2020 07:44:04
User entered 'Hypertension'	Nancy Torrence (b) (4)	25 Sep 2020 07:43:57
	(b) (4)	

US3252553

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'UN UNK 2000'	Nancy Torrence (b) (4)	25 Sep 2020 07:43:57
	(b) (4)	

US3252553

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:15:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '0'	Nancy Torrence (b) (4)	25 Sep 2020 07:43:57
	(b) (4)	

US3252553

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:15:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	25 Sep 2020 07:43:57
	(b) (4)	

US3252553

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	Nancy Torrence (b) (4)	25 Sep 2020 07:43:57
	(b) (4)	

US3252553

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:15:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '0'	Nancy Torrence (b) (4)	25 Sep 2020 07:43:57
	(b) (4)	

US3252553

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:15:52

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered 'Jan 2000'	System	25 Sep 2020 07:43:57

US3252553

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered '2000'	System	25 Sep 2020 07:43:57

US3252553

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered empty.	System	25 Sep 2020 07:43:57

US3252553

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered empty.	System	25 Sep 2020 07:43:57

US3252553

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:15:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac device therapeutic procedures, PT: Cardiac pacemaker insertion, LLT: Cardiac pacemaker insertion - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 07:45:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	25 Sep 2020 07:45:04
User entered 'Pacemaker'	Nancy Torrence (b) (4)	25 Sep 2020 07:44:46
	(b) (4)	

US3252553

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'UN UNK 2018'	Nancy Torrence (b) (4)	25 Sep 2020 07:44:46
	(b) (4)	

US3252553

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:15:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '0'	Nancy Torrence (b) (4)	25 Sep 2020 07:44:46
	(b) (4)	

US3252553

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:15:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	25 Sep 2020 07:44:46
	(b) (4)	

US3252553

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	Nancy Torrence (b) (4)	25 Sep 2020 07:44:46
	(b) (4)	

US3252553

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:15:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '0'	Nancy Torrence (b) (4)	25 Sep 2020 07:44:46
	(b) (4)	

US3252553

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:15:52

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered 'Jan 2018'	System	25 Sep 2020 07:44:46

US3252553

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered '2018'	System	25 Sep 2020 07:44:46

US3252553

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered empty.	System	25 Sep 2020 07:44:46

US3252553

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered empty.	System	25 Sep 2020 07:44:46

US3252553

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:15:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Bradycardia, LLT: Bradycardia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 07:46:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 07:46:49
Data point term sent to Coder	System	25 Sep 2020 07:46:05
User entered 'Bradycardia'	Nancy Torrence (b) (4) (b) (4)	25 Sep 2020 07:45:45

US3252553

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'UN UNK 2018'	Nancy Torrence (b) (4)	25 Sep 2020 07:45:45
	(b) (4)	

US3252553

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:15:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '0'	Nancy Torrence (b) (4)	25 Sep 2020 07:45:45
	(b) (4)	

US3252553

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:15:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'No (N)'	Nancy Torrence (b) (4)	25 Sep 2020 07:45:45
	(b) (4)	

US3252553

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'UN UNK 2018'	Nancy Torrence (b) (4)	25 Sep 2020 07:45:45
	(b) (4)	

US3252553

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:15:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '0'	Nancy Torrence (b) (4)	25 Sep 2020 07:45:45
	(b) (4)	

US3252553

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:15:52

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered 'Jan 2018'	System	25 Sep 2020 07:45:45

US3252553

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered '2018'	System	25 Sep 2020 07:45:45

US3252553

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered 'Jan 2018'	System	25 Sep 2020 07:45:45

US3252553

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered '2018'	System	25 Sep 2020 07:45:45

US3252553

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	25 Sep 2020 07:47:38
	(b) (4)	

US3252553

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '24 Sep 2020'	Nancy Torrence (b) (4)	25 Sep 2020 07:47:38
	(b) (4)	

US3252553

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '15:36'	Nancy Torrence (b) (4)	25 Sep 2020 07:47:38
	(b) (4)	

US3252553

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered '24 Sep 2020 15:36'	System	25 Sep 2020 07:47:38

US3252553

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '75' in	Nancy Torrence (b) (4)	25 Sep 2020 07:47:38
DataPoint set to visible.	(b) (4) System	24 Sep 2020 21:32:54

US3252553

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '285.8' lb	Nancy Torrence (b) (4)	25 Sep 2020 07:47:38
DataPoint set to visible.	(b) (4) System	24 Sep 2020 21:32:54

US3252553

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered '35.79724'	System	25 Sep 2020 07:47:38
DataPoint set to visible.	System	24 Sep 2020 21:32:54

US3252553

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered 'kg/m2'	System	25 Sep 2020 07:47:38
DataPoint set to visible.	System	24 Sep 2020 21:32:54

US3252553

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered missing code ND - Not Done.	Nancy Torrence (b) (4)	25 Sep 2020 07:47:38
	(b) (4)	

US3252553

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	Nancy Torrence (b) (4)	25 Sep 2020 07:47:38
	(b) (4)	

US3252553

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	Nancy Torrence (b) (4)	25 Sep 2020 07:47:38
	(b) (4)	

US3252553

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered missing code ND - Not Done.	Nancy Torrence (b) (4)	25 Sep 2020 07:47:38
	(b) (4)	

US3252553

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered 'bpm'	System	25 Sep 2020 07:47:38

US3252553

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered missing code ND - Not Done.	Nancy Torrence (b) (4)	25 Sep 2020 07:47:38
	(b) (4)	

US3252553

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered 'breaths/min'	System	25 Sep 2020 07:47:38

US3252553

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered missing code ND - Not Done.	Nancy Torrence (b) (4)	25 Sep 2020 07:47:38
	(b) (4)	

US3252553

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered 'mmHg'	System	25 Sep 2020 07:47:38

US3252553

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered missing code ND - Not Done.	Nancy Torrence (b) (4)	25 Sep 2020 07:47:38
	(b) (4)	

US3252553

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered 'mmHg'	System	25 Sep 2020 07:47:38

US3252553

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18

US3252553

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18

US3252553

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:15:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	25 Sep 2020 07:47:49
	(b) (4)	

US3252553

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:15:52

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '24 Sep 2020'	Nancy Torrence (b) (4)	25 Sep 2020 07:47:49
	(b) (4)	

US3252553

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:42:52

US3252553

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:42:52

US3252553

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:42:52

US3252553

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:42:52

US3252553

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:42:52

US3252553

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:42:52

US3252553

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:42:52

US3252553

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:42:52

US3252553

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:42:52

US3252553

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:42:52

US3252553

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:42:52

US3252553

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:15:52

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:42:52

US3252553

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:15:52

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'Security guard'	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:42:52

US3252553

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:15:52

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '0'	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:42:52

US3252553

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '0'	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:42:52

US3252553

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '0'	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:42:52

US3252553

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '0'	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:42:52

US3252553

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '0'	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:42:52

US3252553

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'I'	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:42:52

US3252553

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:15:52

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '0'	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:42:52

US3252553

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:15:52

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:42:52

US3252553

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'Yes (Y)'	Joanna Gurrola Mahoney	24 Sep 2020 21:14:03
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '24 Sep 2020'	Joanna Gurrola Mahoney	24 Sep 2020 21:14:03
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'Clinic (Clinic)'	Joanna Gurrola Mahoney	24 Sep 2020 21:14:03
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered 'VISIT1'	System	24 Sep 2020 21:14:03

US3252553

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '24 SEP 2020'	RWS_ENDPOINT	24 Sep 2020 20:44:21
	ENDPOINT (b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '191363'	RWS_ENDPOINT	24 Sep 2020 20:44:21
	ENDPOINT (b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 20:44:21

US3252553

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:15:52

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:43:20

US3252553

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:15:52

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:43:20

US3252553

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'No (N)'	Joanna Gurrola Mahoney	24 Sep 2020 21:43:20
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:43:20

US3252553

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:15:52

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:43:20

US3252553

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'No (N)'	Joanna Gurrola Mahoney	24 Sep 2020 21:43:20
DataPoint set to visible.	(b) (4) System	24 Sep 2020 21:32:54

US3252553

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:15:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered missing code ND - Not Done.	Nancy Torrence (b) (4)	25 Sep 2020 07:53:42
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:15:52

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered missing code ND - Not Done.	Nancy Torrence (b) (4)	25 Sep 2020 07:53:42
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:15:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered missing code ND - Not Done.	Nancy Torrence (b) (4)	25 Sep 2020 07:53:42
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:15:52

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered missing code ND - Not Done.	Nancy Torrence (b) (4)	25 Sep 2020 07:53:42
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User accepted default value 'Pre-Dose (PREDOSE)'	Nancy Torrence (b) (4) (b) (4)	25 Sep 2020 07:53:42

US3252553

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	25 Sep 2020 07:53:42
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '24 Sep 2020'	Nancy Torrence (b) (4)	25 Sep 2020 07:53:42
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '15:36'	Nancy Torrence (b) (4)	25 Sep 2020 07:53:42
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered '24 Sep 2020 15:36'	System	25 Sep 2020 07:53:42

US3252553

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	25 Sep 2020 07:54:28
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	25 Sep 2020 07:54:28
User entered '98.6' F reason for change: Data Entry Error	Nancy Torrence (b) (4) (b) (4)	25 Sep 2020 07:54:28
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	25 Sep 2020 07:53:42
User entered '59' F	Nancy Torrence (b) (4) (b) (4)	25 Sep 2020 07:53:42

US3252553

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'Oral (Oral)'	Nancy Torrence (b) (4)	25 Sep 2020 07:53:42
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	Nancy Torrence (b) (4)	25 Sep 2020 07:53:42
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '60'	Nancy Torrence (b) (4)	25 Sep 2020 07:53:42
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered 'bpm'	System	25 Sep 2020 07:53:42

US3252553

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '16'	Nancy Torrence (b) (4)	25 Sep 2020 07:53:42
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered 'breaths/min'	System	25 Sep 2020 07:53:42

US3252553

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '137'	Nancy Torrence (b) (4)	25 Sep 2020 07:53:42
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered 'mmHg'	System	25 Sep 2020 07:53:42

US3252553

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '81'	Nancy Torrence (b) (4)	25 Sep 2020 07:53:42
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered 'mmHg'	System	25 Sep 2020 07:53:42

US3252553

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:15:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered missing code ND - Not Done.	Nancy Torrence (b) (4)	25 Sep 2020 07:53:42
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:15:52

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered missing code ND - Not Done.	Nancy Torrence (b) (4)	25 Sep 2020 07:53:42
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User accepted default value 'Post-Dose (POSTDOSE)'	Nancy Torrence (b) (4) (b) (4)	25 Sep 2020 07:53:42

US3252553

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	25 Sep 2020 07:53:42
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '24 Sep 2020'	Nancy Torrence (b) (4)	25 Sep 2020 07:53:42
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '16:36'	Nancy Torrence (b) (4)	25 Sep 2020 07:53:42
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered '24 Sep 2020 16:36'	System	25 Sep 2020 07:53:42

US3252553

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '98.6' F	Nancy Torrence (b) (4)	25 Sep 2020 07:53:42
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'Oral (Oral)'	Nancy Torrence (b) (4)	25 Sep 2020 07:53:42
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	Nancy Torrence (b) (4)	25 Sep 2020 07:53:42
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '59'	Nancy Torrence (b) (4)	25 Sep 2020 07:53:42
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered 'bpm'	System	25 Sep 2020 07:53:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '18'	Nancy Torrence (b) (4)	25 Sep 2020 07:53:42
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered 'breaths/min'	System	25 Sep 2020 07:53:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '115'	Nancy Torrence (b) (4)	25 Sep 2020 07:53:42
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered 'mmHg'	System	25 Sep 2020 07:53:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '74'	Nancy Torrence (b) (4)	25 Sep 2020 07:53:42
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered 'mmHg'	System	25 Sep 2020 07:53:42

US3252553

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:15:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'No (N)'	Nancy Torrence (b) (4)	25 Sep 2020 07:58:07
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:15:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	Nancy Torrence (b) (4)	25 Sep 2020 07:58:07
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'Yes (Y)'	Joanna Gurrola Mahoney	24 Sep 2020 21:34:30
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	Joanna Gurrola Mahoney	24 Sep 2020 21:34:30
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	Joanna Gurrola Mahoney (b) (4)	24 Sep 2020 21:34:30

US3252553

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered 'MRNA-1273 OR PLACEBO'	System	24 Sep 2020 21:34:30

US3252553

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '24 Sep 2020'	Joanna Gurrola Mahoney	24 Sep 2020 21:34:30
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '16:06'	Joanna Gurrola Mahoney	24 Sep 2020 21:34:30
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered '24 Sep 2020 16:06'	System	24 Sep 2020 21:34:30

US3252553

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'Left Arm (LEFT ARM)'	Joanna Gurrola Mahoney	24 Sep 2020 21:34:30
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered 'ONCE'	System	24 Sep 2020 21:34:30

US3252553

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered 'INTRAMUSCULAR'	System	24 Sep 2020 21:34:30

US3252553

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	25 Sep 2020 07:58:38
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '24 Sep 2020'	Nancy Torrence (b) (4)	25 Sep 2020 07:58:38
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '15:47'	Nancy Torrence (b) (4)	25 Sep 2020 07:58:38
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered '24 Sep 2020 15:47'	System	25 Sep 2020 07:58:38

US3252553

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:15:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '24 Sep 2020'	Nancy Torrence (b) (4)	25 Sep 2020 08:09:48
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:15:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Nancy Torrence (b) (4) (b) (4)	25 Sep 2020 08:09:48

US3252553

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:15:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	25 Sep 2020 08:09:48
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:15:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '15:44'	Nancy Torrence (b) (4)	25 Sep 2020 08:09:48
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered '24 Sep 2020 15:44'	System	25 Sep 2020 08:09:48

US3252553

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:15:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Nancy Torrence (b) (4) (b) (4)	25 Sep 2020 08:09:48

US3252553

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:15:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'No (N)'	Nancy Torrence (b) (4)	25 Sep 2020 08:09:48
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:15:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	Nancy Torrence (b) (4)	25 Sep 2020 08:09:48
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:15:52

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered empty.	System	25 Sep 2020 08:09:48

US3252553

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	25 Sep 2020 08:09:55
	(b) (4)	

US3252553

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered 'I'	System	25 Sep 2020 08:09:55

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
Data entry locked.	System	24 Sep 2020 21:34:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-24T16:38:22', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '5165b529-9a75-4c90-bdb5-c877da5814b3'	System	24 Sep 2020 21:38:58
User entered 'Yes (Y)'	System	24 Sep 2020 21:38:58

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-24T16:38:38', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '5165b529-9a75-4c90-bdb5-c877da5814b3'	System	24 Sep 2020 21:38:58
User entered '98.6'	System	24 Sep 2020 21:38:58

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-24T16:38:48', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '5165b529-9a75-4c90-bdb5-c877da5814b3'	System	24 Sep 2020 21:38:58
User entered 'No (N)'	System	24 Sep 2020 21:38:58

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-24T16:38:53', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '5165b529-9a75-4c90-bdb5-c877da5814b3'	System	24 Sep 2020 21:38:58
User entered '24 Sep 2020 16:38'	System	24 Sep 2020 21:38:58

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '24 Sep 2020 16:26'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '24 Sep 2020 18:56'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
Data entry locked.	System	24 Sep 2020 21:34:30
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '24 Sep 2020 19:51'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
Data entry locked.	System	24 Sep 2020 21:34:30
User entered 'Day 2'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:15:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-25T13:54:07', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '9962c332-bf3a-4d77-8bbe-78d8f6b3bc9f'	System	25 Sep 2020 18:55:12
User entered 'No (N)'	System	25 Sep 2020 18:55:12

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-25T13:54:22', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '9962c332-bf3a-4d77-8bbe-78d8f6b3bc9f'	System	25 Sep 2020 18:55:12
User entered 'No (N)'	System	25 Sep 2020 18:55:12

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-25T13:55:09', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '9962c332-bf3a-4d77-8bbe-78d8f6b3bc9f'	System	25 Sep 2020 18:55:12
User entered '25 Sep 2020 13:55'	System	25 Sep 2020 18:55:12

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
Data entry locked.	System	24 Sep 2020 21:34:30
User entered 'Day 3'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:15:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-26T16:27:28', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '744b4d16-3170-491f-a6c8-3aff908eebed'	System	26 Sep 2020 21:27:55
User entered 'Yes (Y)'	System	26 Sep 2020 21:27:55

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:15:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-26T16:27:13', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '744b4d16-3170-491f-a6c8-3aff908eebed'	System	26 Sep 2020 21:27:55
User entered '96.2'	System	26 Sep 2020 21:27:55

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-26T16:27:19', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '744b4d16-3170-491f-a6c8-3aff908eebed'	System	26 Sep 2020 21:27:55
User entered 'No (N)'	System	26 Sep 2020 21:27:55

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-26T16:27:52', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '744b4d16-3170-491f-a6c8-3aff908eebed'	System	26 Sep 2020 21:27:55
User entered '26 Sep 2020 16:27'	System	26 Sep 2020 21:27:55

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
Data entry locked.	System	24 Sep 2020 21:34:30
User entered 'Day 4'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:15:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-27T21:04:45', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'cc879a80-8767-4529-9ba1-4efe4377f34f'	System	28 Sep 2020 02:05:07
User entered 'Yes (Y)'	System	28 Sep 2020 02:05:07

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:15:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-27T21:04:29', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'cc879a80-8767-4529-9ba1-4efe4377f34f' User entered '97.0'	System	28 Sep 2020 02:05:07
	System	28 Sep 2020 02:05:07

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-27T21:04:36', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'cc879a80-8767-4529-9ba1-4efe4377f34f'	System	28 Sep 2020 02:05:07
User entered 'No (N)'	System	28 Sep 2020 02:05:07

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-27T21:05:03', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'cc879a80-8767-4529-9ba1-4efe4377f34f'	System	28 Sep 2020 02:05:07
User entered '27 Sep 2020 21:05'	System	28 Sep 2020 02:05:07

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
Data entry locked.	System	24 Sep 2020 21:34:30
User entered 'Day 5'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:15:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:15:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:15:52

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
Data entry locked.	System	24 Sep 2020 21:34:30
User entered 'Day 6'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:15:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-29T14:12:13', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '748f7424-3388-42a3-b475-4432dc91a709'	System	29 Sep 2020 19:12:26
User entered 'Yes (Y)'	System	29 Sep 2020 19:12:26

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:15:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-29T14:11:58', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '748f7424-3388-42a3-b475-4432dc91a709'	System	29 Sep 2020 19:12:26
User entered '96.7'	System	29 Sep 2020 19:12:26

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-29T14:12:04', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '748f7424-3388-42a3-b475-4432dc91a709'	System	29 Sep 2020 19:12:26
User entered 'No (N)'	System	29 Sep 2020 19:12:26

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-29T14:12:21', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '748f7424-3388-42a3-b475-4432dc91a709'	System	29 Sep 2020 19:12:26
User entered '29 Sep 2020 14:12'	System	29 Sep 2020 19:12:26

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
Data entry locked.	System	24 Sep 2020 21:34:30
User entered 'Day 7'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:15:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-30T14:46:07', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '1c68ead1-bd34-49fa-8923-e4279bdce76a'	System	30 Sep 2020 19:46:27
User entered 'Yes (Y)'	System	30 Sep 2020 19:46:27

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:15:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-30T14:45:53', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '1c68ead1-bd34-49fa-8923-e4279bdce76a'	System	30 Sep 2020 19:46:27
User entered '96.5'	System	30 Sep 2020 19:46:27

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-30T14:45:58', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '1c68ead1-bd34-49fa-8923-e4279bdce76a'	System	30 Sep 2020 19:46:27
User entered 'No (N)'	System	30 Sep 2020 19:46:27

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-30T14:46:21', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '1c68ead1-bd34-49fa-8923-e4279bdce76a'	System	30 Sep 2020 19:46:27
User entered '30 Sep 2020 14:46'	System	30 Sep 2020 19:46:27

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
Data entry locked.	System	24 Sep 2020 21:34:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-24T16:39:03', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '184d8f82-86fb-4120-86f4-123f17360c0b'	System	24 Sep 2020 21:39:37
User entered 'None (1)'	System	24 Sep 2020 21:39:37

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-24T16:39:09', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '184d8f82-86fb-4120-86f4-123f17360c0b'	System	24 Sep 2020 21:39:37
User entered 'No (N)'	System	24 Sep 2020 21:39:37

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-24T16:39:14', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '184d8f82-86fb-4120-86f4-123f17360c0b'	System	24 Sep 2020 21:39:37
User entered 'No (N)'	System	24 Sep 2020 21:39:37

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-24T16:39:24', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '184d8f82-86fb-4120-86f4-123f17360c0b'	System	24 Sep 2020 21:39:37
User entered 'None (1)'	System	24 Sep 2020 21:39:37

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-24T16:39:33', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '184d8f82-86fb-4120-86f4-123f17360c0b'	System	24 Sep 2020 21:39:37
User entered '24 Sep 2020 16:39'	System	24 Sep 2020 21:39:37

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '24 Sep 2020 16:26'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '24 Sep 2020 18:56'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
Data entry locked.	System	24 Sep 2020 21:34:30
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '24 Sep 2020 19:51'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
Data entry locked.	System	24 Sep 2020 21:34:30
User entered 'Day 2'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-25T13:59:00', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '5425ece7-5295-466b-843a-8b4e6effad9b'	System	25 Sep 2020 18:59:30
User entered 'None (1)'	System	25 Sep 2020 18:59:30

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-25T13:57:17', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '5425ece7-5295-466b-843a-8b4e6effad9b'	System	25 Sep 2020 18:59:30
User entered 'No (N)'	System	25 Sep 2020 18:59:30

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-25T13:57:34', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '5425ece7-5295-466b-843a-8b4e6effad9b'	System	25 Sep 2020 18:59:30
User entered 'No (N)'	System	25 Sep 2020 18:59:30

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-25T13:57:59', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '5425ece7-5295-466b-843a-8b4e6effad9b'	System	25 Sep 2020 18:59:30
User entered 'None (1)'	System	25 Sep 2020 18:59:30

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-25T13:59:25', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '5425ece7-5295-466b-843a-8b4e6effad9b'	System	25 Sep 2020 18:59:30
User entered '25 Sep 2020 13:59'	System	25 Sep 2020 18:59:30

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
Data entry locked.	System	24 Sep 2020 21:34:30
User entered 'Day 3'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-26T16:28:35', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '08fcd4f3-1089-4701-b365-bbcb26c8da59'	System	26 Sep 2020 21:30:08
User entered 'Does not interfere with activity (2)'	System	26 Sep 2020 21:30:08

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:15:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-26T16:28:42', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '08fcd4f3-1089-4701-b365-bbcb26c8da59'	System	26 Sep 2020 21:30:08
User entered 'No (N)'	System	26 Sep 2020 21:30:08

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-26T16:29:15', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '08fcd4f3-1089-4701-b365-bbcb26c8da59'	System	26 Sep 2020 21:30:08
User entered 'No (N)'	System	26 Sep 2020 21:30:08

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-26T16:29:49', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '08fcd4f3-1089-4701-b365-bbcb26c8da59'	System	26 Sep 2020 21:30:08
User entered 'None (1)'	System	26 Sep 2020 21:30:08

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-26T16:30:05', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '08fcd4f3-1089-4701-b365-bbcb26c8da59'	System	26 Sep 2020 21:30:08
User entered '26 Sep 2020 16:30'	System	26 Sep 2020 21:30:08

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
Data entry locked.	System	24 Sep 2020 21:34:30
User entered 'Day 4'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-27T21:05:50', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'd65ea26a-fbab-4e6a-8e37-619cacfe8764'	System	28 Sep 2020 02:06:43
User entered 'Does not interfere with activity (2)'	System	28 Sep 2020 02:06:43

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:15:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-27T21:06:31', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'd65ea26a-fbab-4e6a-8e37-619cacfe8764'	System	28 Sep 2020 02:06:43
User entered 'No (N)'	System	28 Sep 2020 02:06:43

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-27T21:06:03', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'd65ea26a-fbab-4e6a-8e37-619cacfe8764'	System	28 Sep 2020 02:06:43
User entered 'No (N)'	System	28 Sep 2020 02:06:43

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-27T21:06:12', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'd65ea26a-fbab-4e6a-8e37-619cacfe8764'	System	28 Sep 2020 02:06:43
User entered 'None (1)'	System	28 Sep 2020 02:06:43

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-27T21:06:39', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'd65ea26a-fbab-4e6a-8e37-619cacfe8764'	System	28 Sep 2020 02:06:43
User entered '27 Sep 2020 21:06'	System	28 Sep 2020 02:06:43

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
Data entry locked.	System	24 Sep 2020 21:34:30
User entered 'Day 5'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:15:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:15:52

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:15:52

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
Data entry locked.	System	24 Sep 2020 21:34:30
User entered 'Day 6'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-29T14:13:21', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'fd313f2a-e833-4d49-bf56-648226e52125'	System	29 Sep 2020 19:15:23
User entered 'None (1)'	System	29 Sep 2020 19:15:23

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:15:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-29T14:13:25', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'fd313f2a-e833-4d49-bf56-648226e52125'	System	29 Sep 2020 19:15:23
User entered 'No (N)'	System	29 Sep 2020 19:15:23

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-29T14:13:31', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'fd313f2a-e833-4d49-bf56-648226e52125'	System	29 Sep 2020 19:15:23
User entered 'No (N)'	System	29 Sep 2020 19:15:23

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-29T14:14:59', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'fd313f2a-e833-4d49-bf56-648226e52125'	System	29 Sep 2020 19:15:23
User entered 'None (1)'	System	29 Sep 2020 19:15:23

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-29T14:15:19', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'fd313f2a-e833-4d49-bf56-648226e52125'	System	29 Sep 2020 19:15:23
User entered '29 Sep 2020 14:15'	System	29 Sep 2020 19:15:23

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
Data entry locked.	System	24 Sep 2020 21:34:30
User entered 'Day 7'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-30T14:47:00', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'cafa8480-a65d-4757-853f-f43261716892'	System	30 Sep 2020 19:47:50
User entered 'Does not interfere with activity (2)'	System	30 Sep 2020 19:47:50

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-30T14:47:08', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'cafa8480-a65d-4757-853f-f43261716892'	System	30 Sep 2020 19:47:50
User entered 'No (N)'	System	30 Sep 2020 19:47:50

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-30T14:47:15', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'cafa8480-a65d-4757-853f-f43261716892'	System	30 Sep 2020 19:47:50
User entered 'No (N)'	System	30 Sep 2020 19:47:50

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-30T14:47:34', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'cafa8480-a65d-4757-853f-f43261716892'	System	30 Sep 2020 19:47:50
User entered 'Does not interfere with activity (2)'	System	30 Sep 2020 19:47:50

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-30T14:47:46', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'cafa8480-a65d-4757-853f-f43261716892'	System	30 Sep 2020 19:47:50
User entered '30 Sep 2020 14:47'	System	30 Sep 2020 19:47:50

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
Data entry locked.	System	24 Sep 2020 21:34:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-24T16:39:42', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'e2f5bb74-95a1-46f8-b949-bf8332d32919'	System	24 Sep 2020 21:40:49
User entered 'None (0)'	System	24 Sep 2020 21:40:49

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-24T16:39:50', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'e2f5bb74-95a1-46f8-b949-bf8332d32919'	System	24 Sep 2020 21:40:49
User entered 'None (0)'	System	24 Sep 2020 21:40:49

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-24T16:39:56', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'e2f5bb74-95a1-46f8-b949-bf8332d32919'	System	24 Sep 2020 21:40:49
User entered 'None (0)'	System	24 Sep 2020 21:40:49

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-24T16:40:15', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'e2f5bb74-95a1-46f8-b949-bf8332d32919'	System	24 Sep 2020 21:40:49
User entered 'None (0)'	System	24 Sep 2020 21:40:49

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-24T16:40:20', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'e2f5bb74-95a1-46f8-b949-bf8332d32919'	System	24 Sep 2020 21:40:49
User entered 'None (0)'	System	24 Sep 2020 21:40:49

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-24T16:40:32', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'e2f5bb74-95a1-46f8-b949-bf8332d32919'	System	24 Sep 2020 21:40:49
User entered 'None (0)'	System	24 Sep 2020 21:40:49

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

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)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-24T16:40:39', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'e2f5bb74-95a1-46f8-b949-bf8332d32919'	System	24 Sep 2020 21:40:49
User entered 'No (N)'	System	24 Sep 2020 21:40:49

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-24T16:40:45', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'e2f5bb74-95a1-46f8-b949-bf8332d32919'	System	24 Sep 2020 21:40:49
User entered '24 Sep 2020 16:40'	System	24 Sep 2020 21:40:49

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '24 Sep 2020 16:26'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '24 Sep 2020 18:56'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
Data entry locked.	System	24 Sep 2020 21:34:30
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

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)	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '24 Sep 2020 19:51'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
Data entry locked.	System	24 Sep 2020 21:34:30
User entered 'Day 2'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-25T14:46:49', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '8df8b557-6793-4493-9f09-e281a1cbfdb4'	System	25 Sep 2020 19:47:58
User entered 'None (0)'	System	25 Sep 2020 19:47:58

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-25T14:46:54', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '8df8b557-6793-4493-9f09-e281a1cbfdb4'	System	25 Sep 2020 19:47:58
User entered 'None (0)'	System	25 Sep 2020 19:47:58

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-25T14:47:01', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '8df8b557-6793-4493-9f09-e281a1cbfdb4'	System	25 Sep 2020 19:47:58
User entered 'None (0)'	System	25 Sep 2020 19:47:58

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-25T14:47:18', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '8df8b557-6793-4493-9f09-e281a1cbfdb4'	System	25 Sep 2020 19:47:58
User entered 'None (0)'	System	25 Sep 2020 19:47:58

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-25T14:47:23', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '8df8b557-6793-4493-9f09-e281a1cbfdb4'	System	25 Sep 2020 19:47:58
User entered 'None (0)'	System	25 Sep 2020 19:47:58

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-25T14:47:27', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '8df8b557-6793-4493-9f09-e281a1cbfdb4'	System	25 Sep 2020 19:47:58
User entered 'None (0)'	System	25 Sep 2020 19:47:58

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

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)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-25T14:47:34', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '8df8b557-6793-4493-9f09-e281a1cbfdb4'	System	25 Sep 2020 19:47:58
User entered 'No (N)'	System	25 Sep 2020 19:47:58

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-25T14:47:55', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '8df8b557-6793-4493-9f09-e281a1cbfdb4'	System	25 Sep 2020 19:47:58
User entered '25 Sep 2020 14:47'	System	25 Sep 2020 19:47:58

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
Data entry locked.	System	24 Sep 2020 21:34:30
User entered 'Day 3'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

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)	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
Data entry locked.	System	24 Sep 2020 21:34:30
User entered 'Day 4'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-27T21:06:51', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'e8c80ff1-1b2f-4ea0-94ed-305c0926ef97'	System	28 Sep 2020 02:08:04
User entered 'None (0)'	System	28 Sep 2020 02:08:04

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-27T21:06:59', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'e8c80ff1-1b2f-4ea0-94ed-305c0926ef97'	System	28 Sep 2020 02:08:04
User entered 'None (0)'	System	28 Sep 2020 02:08:04

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-27T21:07:07', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'e8c80ff1-1b2f-4ea0-94ed-305c0926ef97'	System	28 Sep 2020 02:08:04
User entered 'None (0)'	System	28 Sep 2020 02:08:04

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-27T21:07:12', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'e8c80ff1-1b2f-4ea0-94ed-305c0926ef97'	System	28 Sep 2020 02:08:04
User entered 'None (0)'	System	28 Sep 2020 02:08:04

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-27T21:07:17', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'e8c80ff1-1b2f-4ea0-94ed-305c0926ef97'	System	28 Sep 2020 02:08:04
User entered 'None (0)'	System	28 Sep 2020 02:08:04

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-27T21:07:22', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'e8c80ff1-1b2f-4ea0-94ed-305c0926ef97'	System	28 Sep 2020 02:08:04
User entered 'None (0)'	System	28 Sep 2020 02:08:04

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

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)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-27T21:07:54', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'e8c80ff1-1b2f-4ea0-94ed-305c0926ef97'	System	28 Sep 2020 02:08:04
User entered 'No (N)'	System	28 Sep 2020 02:08:04

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-09-27T21:08:00', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'e8c80ff1-1b2f-4ea0-94ed-305c0926ef97'	System	28 Sep 2020 02:08:04
User entered '27 Sep 2020 21:08'	System	28 Sep 2020 02:08:04

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
Data entry locked.	System	24 Sep 2020 21:34:30
User entered 'Day 5'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:15:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:15:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:15:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:15:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:15:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:15:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:15:52

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)	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:15:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
Data entry locked.	System	24 Sep 2020 21:34:30
User entered 'Day 6'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

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) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
Data entry locked.	System	24 Sep 2020 21:34:30
User entered 'Day 7'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

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)	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:58:25

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 21:34:30

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
Data entry locked.	System	30 Sep 2020 19:47:50
User entered 'Day 8'	System	30 Sep 2020 19:47:50

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-10-01T18:57:01', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '76247c18-c973-4e32-8f70-eab719ca091d'	System	01 Oct 2020 23:57:26
User entered 'None (1)'	System	01 Oct 2020 23:57:26

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-10-01T18:57:22', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '76247c18-c973-4e32-8f70-eab719ca091d'	System	01 Oct 2020 23:57:26
User entered '01 Oct 2020 18:57'	System	01 Oct 2020 23:57:26

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 19:47:50

US3252553

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 19:47:50

US3252553

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
Data entry locked.	System	30 Sep 2020 19:47:50
User entered 'Day 8'	System	30 Sep 2020 19:47:50

US3252553

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:15:52

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)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-10-01T18:57:35', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '50dcd24a-7c87-4bec-a514-7bbfe95a4b47'	System	01 Oct 2020 23:57:48
User entered 'No (N)'	System	01 Oct 2020 23:57:48

US3252553

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:15:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-10-01T18:57:44', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '50dcd24a-7c87-4bec-a514-7bbfe95a4b47'	System	01 Oct 2020 23:57:48
User entered '01 Oct 2020 18:57'	System	01 Oct 2020 23:57:48

US3252553

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 19:47:50

US3252553

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 19:47:50

US3252553

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
Data entry locked.	System	30 Sep 2020 19:47:50
User entered 'Day 8'	System	30 Sep 2020 19:47:50

US3252553

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-10-01T18:58:11', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'd19b6df0-8223-41a3-a88d-fcb9c2bfb725'	System	01 Oct 2020 23:58:23
User entered 'None (1)'	System	01 Oct 2020 23:58:23

US3252553

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2020-10-01T18:58:19', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'd19b6df0-8223-41a3-a88d-fcb9c2bfb725'	System	01 Oct 2020 23:58:23
User entered '01 Oct 2020 18:58'	System	01 Oct 2020 23:58:23

US3252553

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 19:47:50

US3252553

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:25
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 19:47:50

US3252553

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	02 Oct 2020 05:24:24
	(b) (4)	

US3252553

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '1 Oct 2020'	Nancy Torrence (b) (4)	02 Oct 2020 05:24:24
	(b) (4)	

US3252553

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4)	02 Oct 2020 05:24:24
	(b) (4)	

US3252553

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	Nancy Torrence (b) (4)	02 Oct 2020 05:24:24
	(b) (4)	

US3252553

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	02 Oct 2020 05:24:29
	(b) (4)	

US3252553

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered 'I'	System	02 Oct 2020 05:24:29

US3252553

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	09 Oct 2020 03:05:40
	(b) (4)	

US3252553

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '8 Oct 2020'	Nancy Torrence (b) (4)	09 Oct 2020 03:05:40
	(b) (4)	

US3252553

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4)	09 Oct 2020 03:05:40
	(b) (4)	

US3252553

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	Nancy Torrence (b) (4)	09 Oct 2020 03:05:40
	(b) (4)	

US3252553

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	09 Oct 2020 03:05:46
	(b) (4)	

US3252553

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered 'I'	System	09 Oct 2020 03:05:46

US3252553

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	16 Oct 2020 06:15:45
	(b) (4)	

US3252553

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered '15 Oct 2020'	Nancy Torrence (b) (4)	16 Oct 2020 06:15:45
	(b) (4)	

US3252553

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4)	16 Oct 2020 06:15:45
	(b) (4)	

US3252553

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	Nancy Torrence (b) (4)	16 Oct 2020 06:15:45
	(b) (4)	

US3252553

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 09:40:49
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	24 Nov 2020 16:11:19
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	16 Oct 2020 06:15:49

US3252553

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered '1'	System	11 Feb 2021 09:40:49
User entered empty.	System	24 Nov 2020 16:11:19
User entered '1'	System	16 Oct 2020 06:15:49

US3252553

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'No (N)'	(b) (4), (b) (6)	11 Feb 2021 09:40:57

US3252553

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 09:40:57

US3252553

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 09:40:57

US3252553

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered 'VISIT2'	System	11 Feb 2021 09:40:57

US3252553

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Feb 2021 09:41:03

US3252553

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'No (N)'	(b) (4), (b) (6)	11 Feb 2021 09:41:03

US3252553

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 09:41:03

US3252553

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 09:41:03

US3252553

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered empty.	System	11 Feb 2021 09:41:03

US3252553

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 09:41:03

US3252553

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 09:41:03

US3252553

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 09:41:03

US3252553

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 09:41:03

US3252553

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered empty.	System	11 Feb 2021 09:41:03

US3252553

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 09:41:03

US3252553

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered empty.	System	11 Feb 2021 09:41:03

US3252553

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 09:41:03

US3252553

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered empty.	System	11 Feb 2021 09:41:03

US3252553

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 09:41:03

US3252553

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered empty.	System	11 Feb 2021 09:41:03

US3252553

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Feb 2021 09:41:03

US3252553

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'No (N)'	(b) (4), (b) (6)	11 Feb 2021 09:41:03

US3252553

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 09:41:03

US3252553

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 09:41:03

US3252553

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered empty.	System	11 Feb 2021 09:41:03

US3252553

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 09:41:03

US3252553

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 09:41:03

US3252553

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 09:41:03

US3252553

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 09:41:03

US3252553

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered empty.	System	11 Feb 2021 09:41:03

US3252553

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 09:41:03

US3252553

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered empty.	System	11 Feb 2021 09:41:03

US3252553

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 09:41:03

US3252553

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered empty.	System	11 Feb 2021 09:41:03

US3252553

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 09:41:03

US3252553

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered empty.	System	11 Feb 2021 09:41:03

US3252553

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:15:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'No (N)'	(b) (4), (b) (6)	11 Feb 2021 09:41:08

US3252553

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:15:52

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 09:41:08

US3252553

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'No (N)'	(b) (4), (b) (6)	11 Feb 2021 09:41:13

US3252553

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
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).		11 Feb 2021 09:41:36
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 09:41:36
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	11 Feb 2021 09:41:13
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 09:41:13

US3252553

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'subject visit is scheduled' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 09:41:36
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 09:41:13

US3252553

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered empty.	System	11 Feb 2021 09:41:13

US3252553

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 09:41:13

US3252553

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 09:41:13

US3252553

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered empty.	System	11 Feb 2021 09:41:13

US3252553

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 09:41:13

US3252553

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered empty.	System	11 Feb 2021 09:41:13

US3252553

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered empty.	System	11 Feb 2021 09:41:13

US3252553

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'No (N)'	(b) (4), (b) (6)	11 Feb 2021 09:41:41

US3252553

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 09:41:41

US3252553

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 09:41:41

US3252553

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered empty.	System	11 Feb 2021 09:41:41

US3252553

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:15:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 09:41:47

US3252553

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:15:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	11 Feb 2021 09:41:47

US3252553

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:15:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'No (N)'	(b) (4), (b) (6)	11 Feb 2021 09:41:47

US3252553

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:15:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 09:41:47

US3252553

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered empty.	System	11 Feb 2021 09:41:47

US3252553

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:15:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	11 Feb 2021 09:41:47

US3252553

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:15:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'No (N)'	(b) (4), (b) (6)	11 Feb 2021 09:41:47

US3252553

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:15:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 09:41:47

US3252553

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:15:52

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered empty.	System	11 Feb 2021 09:41:47

US3252553

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:18:20
User entered 'No (N)'	(b) (4), (b) (6)	11 Feb 2021 09:41:52

US3252553

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:23:25
User entered empty.	System	11 Feb 2021 09:41:52

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
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US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
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US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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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US3252553

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
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US3252553

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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US3252553

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3252553

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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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US3252553

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3252553

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
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US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
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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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[Date and time of submission](#)

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DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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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US3252553

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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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US3252553

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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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US3252553

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	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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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US3252553

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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 (3bf3f7548fec1faf)', Time: '2021-04-10T01:41:11', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '48f5f320-25fe-43b3-b8a3-308a59b6922b'	System	10 Apr 2021 06:41:59
User entered 'No (N)'	System	10 Apr 2021 06:41:59
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you been exposed to someone with known SARS-CoV-2 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 (3bf3f7548fec1faf)', Time: '2021-04-10T01:41:22', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '48f5f320-25fe-43b3-b8a3-308a59b6922b'	System	10 Apr 2021 06:41:59
User entered 'No (N)'	System	10 Apr 2021 06:41:59
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2021-04-10T01:41:54', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '48f5f320-25fe-43b3-b8a3-308a59b6922b'	System	10 Apr 2021 06:41:59
User entered '10 Apr 2021 01:41:54'	System	10 Apr 2021 06:41:59
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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 (3bf3f7548fec1faf)', Time: '2021-04-25T00:15:30', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'a29f6577-4552-498e-ac7b-6508fe149478'	System	25 Apr 2021 05:16:27
User entered 'No (N)'	System	25 Apr 2021 05:16:27
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you been exposed to someone with known SARS-CoV-2 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 (3bf3f7548fec1faf)', Time: '2021-04-25T00:15:42', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'a29f6577-4552-498e-ac7b-6508fe149478'	System	25 Apr 2021 05:16:27
User entered 'No (N)'	System	25 Apr 2021 05:16:27
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2021-04-25T00:16:23', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: 'a29f6577-4552-498e-ac7b-6508fe149478'	System	25 Apr 2021 05:16:27
User entered '25 Apr 2021 00:16:23'	System	25 Apr 2021 05:16:27
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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 (3bf3f7548fec1faf)', Time: '2021-05-01T00:27:46', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '24c40a2c-d8a7-4313-b5a6-698b508e9093'	System	01 May 2021 05:32:41
User entered 'No (N)'	System	01 May 2021 05:32:41
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you been exposed to someone with known SARS-CoV-2 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 (3bf3f7548fec1faf)', Time: '2021-05-01T00:27:39', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '24c40a2c-d8a7-4313-b5a6-698b508e9093'	System	01 May 2021 05:32:41
User entered 'No (N)'	System	01 May 2021 05:32:41
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2021-05-01T00:28:08', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '24c40a2c-d8a7-4313-b5a6-698b508e9093'	System	01 May 2021 05:32:41
User entered '01 May 2021 00:28:08'	System	01 May 2021 05:32:41
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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)

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[Date and time of submission](#)

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US3252553

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
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Folder: New Safety Follow Up Diary (1)

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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
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US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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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US3252553

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
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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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US3252553

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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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US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
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US3252553

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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US3252553

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Please 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	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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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US3252553

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
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US3252553

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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US3252553

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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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US3252553

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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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US3252553

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Please contact your study clinic 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	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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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DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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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US3252553

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	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
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US3252553

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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US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
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US3252553

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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US3252553

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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US3252553

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 10:44:13

US3252553

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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US3252553

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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DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

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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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US3252553

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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DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

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	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

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[Congestion](#)

Audit	User	Time (GMT)
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

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[Patient Cloud Open Date & Time](#)

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DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

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TIMEPOINT

Audit	User	Time (GMT)
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Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 10:44:13

US3252553

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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US3252553

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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Fever (Temperature \geq 100.4°F/38°C)

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US3252553

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

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US3252553

Folder: New Safety Follow Up Diary (1)

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[Cough](#)

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US3252553

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
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DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

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US3252553

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[Muscle aches](#)

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US3252553

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[Body aches](#)

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DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

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[New loss of taste](#)

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[New loss of smell](#)

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US3252553

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

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US3252553

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[Congestion](#)

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[Runny nose](#)

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US3252553

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[Nausea](#)

Audit	User	Time (GMT)
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Diarrhea](#)

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[Patient Cloud Open Date & Time](#)

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DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

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DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 10:44:13

US3252553

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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US3252553

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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US3252553

Folder: New Safety Follow Up Diary (1)

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Fever (Temperature \geq 100.4°F/38°C)

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US3252553

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[Chills](#)

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[Cough](#)

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US3252553

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

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US3252553

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[Difficulty breathing](#)

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US3252553

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[Fatigue](#)

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US3252553

Folder: New Safety Follow Up Diary (1)

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[Muscle aches](#)

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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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US3252553

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3252553

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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

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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
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US3252553

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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US3252553

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
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US3252553

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US3252553

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	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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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US3252553

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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US3252553

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
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US3252553

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US3252553

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	08 Mar 2021 07:27:03
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US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

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	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
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Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

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US3252553

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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US3252553

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Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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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US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
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US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3252553

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
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US3252553

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	08 Mar 2021 07:27:03
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US3252553

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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US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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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US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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](#)

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
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US3252553

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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US3252553

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
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US3252553

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	08 Mar 2021 07:27:03
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US3252553

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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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US3252553

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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US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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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US3252553

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3252553

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 10:44:13

US3252553

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?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

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	08 Mar 2021 07:27:03
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US3252553

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US3252553

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	08 Mar 2021 07:27:03
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US3252553

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	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

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	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

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	08 Mar 2021 07:27:03
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US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
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[Congestion](#)

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Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

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US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Diarrhea](#)

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DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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US3252553

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
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US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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](#)

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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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US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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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DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
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US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
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US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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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US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

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Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
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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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
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US3252553

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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US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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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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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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US3252553

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	08 Mar 2021 07:27:03
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US3252553

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	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

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DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
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US3252553

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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US3252553

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
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US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
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US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
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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](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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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US3252553

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
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US3252553

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	08 Mar 2021 07:27:03
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US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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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US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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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DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
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US3252553

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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US3252553

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3252553

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
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US3252553

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	08 Mar 2021 07:27:03
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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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US3252553

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	08 Mar 2021 07:27:03
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US3252553

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	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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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US3252553

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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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:15:52

[Have you had 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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US3252553

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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US3252553

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	08 Mar 2021 07:27:03
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US3252553

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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US3252553

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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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US3252553

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	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

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US3252553

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Vomiting](#)

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US3252553

Folder: New Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:15:52

[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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US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
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US3252553

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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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US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
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DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
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US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
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US3252553

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US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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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US3252553

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

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	08 Mar 2021 07:27:03
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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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DataPoint Inactivated.	System	18 Feb 2021 06:25:50

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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.](#)

Audit	User	Time (GMT)
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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	08 Mar 2021 07:27:03
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US3252553

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '19 Nov 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '23 Nov 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with known SARS-CoV-2 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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '26 Nov 2022 00:01'	System	20 Nov 2020 10:44:13

US3252553

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	08 Mar 2021 07:27:03
DataPoint Inactivated.	System	18 Feb 2021 06:25:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:44:13
Amendment Manager: User entered '30 Nov 2022 23:59'	System	20 Nov 2020 10:44:13

US3252553

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:15:52

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)	30 Apr 2021 14:31:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2021-04-13T15:17:31', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '39dbaef7-a419-43f8-bec1-44fda0f528be'	System	13 Apr 2021 20:17:59
User entered 'No (N)'	System	13 Apr 2021 20:17:59

US3252553

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:15:52

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:31:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bf3f7548fec1faf)', Time: '2021-04-13T15:17:53', User OID: 'PatientReportedOutcome (US3252553)', ODM File OID: '39dbaef7-a419-43f8-bec1-44fda0f528be'	System	13 Apr 2021 20:17:59
User entered '13 Apr 2021 15:17:53'	System	13 Apr 2021 20:17:59

US3252553

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

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Mar 2021 03:37:07

US3252553

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

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User closed query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	08 Mar 2021 07:27:03
User opened query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	08 Mar 2021 03:37:07
User entered '5 Mar 2021'	(b) (4), (b) (6)	08 Mar 2021 03:37:07

US3252553

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

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	08 Mar 2021 03:37:07

US3252553

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

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered 'UNBLND_DECIDE'	System	08 Mar 2021 03:37:07

US3252553

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

Form: Unblinding

Generated On: 09 Jun 2021 16:15:52

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered '5 Mar 2021'	(b) (4), (b) (6)	08 Mar 2021 03:38:04

US3252553

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

Form: Unblinding

Generated On: 09 Jun 2021 16:15:52

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered '0'	(b) (4), (b) (6)	08 Mar 2021 03:38:04

US3252553

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

Form: Unblinding

Generated On: 09 Jun 2021 16:15:52

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Mar 2021 03:38:04

US3252553

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

Form: Unblinding

Generated On: 09 Jun 2021 16:15:52

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	08 Mar 2021 03:38:04

US3252553

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

Form: Unblinding

Generated On: 09 Jun 2021 16:15:52

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered '5 Mar 2021'	(b) (4), (b) (6)	08 Mar 2021 03:38:04

US3252553

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

Form: Unblinding

Generated On: 09 Jun 2021 16:15:52

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered 'Placebo (Placebo)' reason for change:	(b) (4), (b) (6)	22 Mar 2021 06:51:35
Data Entry Error		
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	08 Mar 2021 03:38:04

US3252553

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

Form: Unblinding

Generated On: 09 Jun 2021 16:15:52

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User closed query 'PV Query: Per unblinding form the subject was randomized to mRNA-1273 but Actual Dose 1 was reported as Placebo. Please reconcile, else clarify. ' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 13:57:46
Query 'PV Query: Per unblinding form the subject was randomized to mRNA-1273 but Actual Dose 1 was reported as Placebo. Please reconcile, else clarify. ' answered with 'Corrected' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 10:02:00
User opened query 'PV Query: Per unblinding form the subject was randomized to mRNA-1273 but Actual Dose 1 was reported as Placebo. Please reconcile, else clarify. ' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 04:39:29
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	08 Mar 2021 03:38:04

US3252553

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

Form: Unblinding

Generated On: 09 Jun 2021 16:15:52

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered 'Not Administered (NA)'	(b) (4), (b) (6)	08 Mar 2021 03:38:04

US3252553

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

Form: Unblinding

Generated On: 09 Jun 2021 16:15:52

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Mar 2021 03:38:04

US3252553

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

Form: Unblinding

Generated On: 09 Jun 2021 16:15:52

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered '1'	System	08 Mar 2021 03:38:04

US3252553

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

Form: Unblinding

Generated On: 09 Jun 2021 16:15:52

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered 'I'	System	08 Mar 2021 03:38:04

US3252553

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:15:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered missing code ND - Not Done.	(b) (4), (b) (6)	08 Mar 2021 03:51:35

US3252553

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:15:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered missing code ND - Not Done.	(b) (4), (b) (6)	08 Mar 2021 03:51:35

US3252553

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:15:52

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered empty.	System	08 Mar 2021 03:51:35
DataPoint set to visible.	System	08 Mar 2021 03:38:04

US3252553

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:15:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered missing code ND - Not Done.	(b) (4), (b) (6)	08 Mar 2021 03:51:35

US3252553

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:15:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered missing code ND - Not Done.	(b) (4), (b) (6)	08 Mar 2021 03:51:35

US3252553

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:15:52

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered empty.	System	08 Mar 2021 03:51:35
DataPoint set to visible.	System	08 Mar 2021 03:38:04

US3252553

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	08 Mar 2021 03:51:35

US3252553

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Mar 2021 03:51:35

US3252553

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
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	08 Mar 2021 07:27:03
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	08 Mar 2021 03:51:35
User entered '5 Mar 2021'	(b) (4), (b) (6)	08 Mar 2021 03:51:35

US3252553

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered '15:37'	(b) (4), (b) (6)	08 Mar 2021 03:51:35

US3252553

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered '5 Mar 2021 15:37'	System	08 Mar 2021 03:51:35

US3252553

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Mar 2021 03:53:15
User entered '98.5' F reason for change: Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 03:53:15
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Mar 2021 03:51:35
User entered '98.' (non-conformant).	(b) (4), (b) (6)	08 Mar 2021 03:51:35

US3252553

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Mar 2021 07:28:41
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Mar 2021 07:28:41
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 07:28:41
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Mar 2021 03:53:15
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 03:51:35

US3252553

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 03:51:35

US3252553

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Mar 2021 03:53:15
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Mar 2021 03:53:15
User entered '79' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 03:53:15
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Mar 2021 03:51:35
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 03:51:35

US3252553

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered 'bpm'	System	08 Mar 2021 03:53:15
User entered empty.	System	08 Mar 2021 03:51:35

US3252553

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Mar 2021 03:53:15
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Mar 2021 03:53:15
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 03:53:15
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Mar 2021 03:51:35
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 03:51:35

US3252553

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered 'breaths/min'	System	08 Mar 2021 03:53:15
User entered empty.	System	08 Mar 2021 03:51:35

US3252553

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Mar 2021 03:53:15
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Mar 2021 03:53:15
User entered '113' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 03:53:15
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Mar 2021 03:51:35
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 03:51:35

US3252553

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered 'mmHg'	System	08 Mar 2021 03:53:15
User entered empty.	System	08 Mar 2021 03:51:35

US3252553

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Mar 2021 03:53:15
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Mar 2021 03:53:15
User entered '67' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 03:53:15
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Mar 2021 03:51:35
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 03:51:35

US3252553

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered 'mmHg'	System	08 Mar 2021 03:53:15
User entered empty.	System	08 Mar 2021 03:51:35

US3252553

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:15:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered missing code ND - Not Done.	(b) (4), (b) (6)	08 Mar 2021 03:51:35

US3252553

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:15:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered missing code ND - Not Done.	(b) (4), (b) (6)	08 Mar 2021 03:51:35

US3252553

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:15:52

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered empty.	System	08 Mar 2021 03:51:35
DataPoint set to visible.	System	08 Mar 2021 03:38:04

US3252553

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	08 Mar 2021 03:51:35

US3252553

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Mar 2021 03:53:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Mar 2021 03:53:15
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 03:53:15
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Mar 2021 03:51:35
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 03:51:35

US3252553

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
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	08 Mar 2021 07:27:03
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	08 Mar 2021 03:53:15
User entered '5 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 03:53:15
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 03:51:35

US3252553

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered '16:58' reason for change: Data Entry	(b) (4), (b) (6)	08 Mar 2021 03:53:15
Error		
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 03:51:35

US3252553

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered '5 Mar 2021 16:58'	System	08 Mar 2021 03:53:15
User entered empty.	System	08 Mar 2021 03:51:35

US3252553

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered '98.7' F reason for change: Data Entry	(b) (4), (b) (6)	08 Mar 2021 03:53:15
Error		
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 03:51:35

US3252553

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Mar 2021 07:29:02
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Mar 2021 07:29:02
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 07:29:02
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Mar 2021 03:53:15
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 03:51:35

US3252553

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 03:51:35

US3252553

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered '79' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 03:53:15
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 03:51:35

US3252553

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered 'bpm'	System	08 Mar 2021 03:53:15
User entered empty.	System	08 Mar 2021 03:51:35

US3252553

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered '14' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 03:53:15
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 03:51:35

US3252553

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered 'breaths/min'	System	08 Mar 2021 03:53:15
User entered empty.	System	08 Mar 2021 03:51:35

US3252553

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered '118' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 03:53:15
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 03:51:35

US3252553

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered 'mmHg'	System	08 Mar 2021 03:53:15
User entered empty.	System	08 Mar 2021 03:51:35

US3252553

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered '74' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 03:53:15
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 03:51:35

US3252553

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered 'mmHg'	System	08 Mar 2021 03:53:15
User entered empty.	System	08 Mar 2021 03:51:35

US3252553

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

Form: Physical Examination

Generated On: 09 Jun 2021 16:15:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered 'No (N)'	(b) (4), (b) (6)	08 Mar 2021 03:53:39

US3252553

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

Form: Physical Examination

Generated On: 09 Jun 2021 16:15:52

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 03:53:39

US3252553

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

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:24:58
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Mar 2021 03:53:54

US3252553

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

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:24:58
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 03:53:54

US3252553

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

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

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)	27 Apr 2021 16:30:18
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:24:58
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 03:53:54

US3252553

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

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered 'mRNA-1273'	System	08 Mar 2021 03:53:54
DataPoint set to visible.	System	08 Mar 2021 03:38:04

US3252553

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

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:24:58
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
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	08 Mar 2021 07:27:03
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	08 Mar 2021 03:53:54
User entered '5 Mar 2021'	(b) (4), (b) (6)	08 Mar 2021 03:53:54

US3252553

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

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:24:58
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered '16:24'	(b) (4), (b) (6)	08 Mar 2021 03:53:54

US3252553

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

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered '5 Mar 2021 16:24'	System	08 Mar 2021 03:53:54

US3252553

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

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:24:58
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	08 Mar 2021 03:53:54

US3252553

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

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:24:58
User entered 'ONCE'	System	08 Mar 2021 03:53:54

US3252553

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

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered 'INTRAMUSCULAR'	System	08 Mar 2021 03:53:54

US3252553

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Mar 2021 03:54:05

US3252553

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:52

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User closed query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	08 Mar 2021 07:27:03
User opened query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	08 Mar 2021 03:54:05
User entered '5 Mar 2021'	(b) (4), (b) (6)	08 Mar 2021 03:54:05

US3252553

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered '16:00'	(b) (4), (b) (6)	08 Mar 2021 03:54:05

US3252553

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered '5 Mar 2021 16:00'	System	08 Mar 2021 03:54:05

US3252553

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:15:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Mar 2021 03:54:17

US3252553

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:15:52

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
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	08 Mar 2021 07:27:03
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	08 Mar 2021 03:54:17
User entered '5 Mar 2021'	(b) (4), (b) (6)	08 Mar 2021 03:54:17

US3252553

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered '16:00'	(b) (4), (b) (6)	08 Mar 2021 03:54:17

US3252553

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered '5 Mar 2021 16:00'	System	08 Mar 2021 03:54:17

US3252553

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

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Mar 2021 03:54:22

US3252553

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

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:30:18
User entered 'I'	System	08 Mar 2021 03:54:22

US3252553

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:49
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Mar 2021 03:16:37

US3252553

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:49
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered '12 Mar 2021'	(b) (4), (b) (6)	15 Mar 2021 03:16:37

US3252553

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:49
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	15 Mar 2021 03:16:37

US3252553

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:49
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 03:16:37

US3252553

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:49
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Mar 2021 03:16:42

US3252553

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:49
User entered 'I'	System	15 Mar 2021 03:16:42

US3252553

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:49
User entered 'I'	System	15 Mar 2021 03:16:42
DataPoint set to visible.	System	15 Mar 2021 03:16:42

US3252553

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Apr 2021 03:17:20

US3252553

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered '6 Apr 2021'	(b) (4), (b) (6)	07 Apr 2021 03:17:20

US3252553

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	07 Apr 2021 03:17:20

US3252553

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	07 Apr 2021 03:17:20

US3252553

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	07 Apr 2021 03:17:55

US3252553

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Apr 2021 03:17:55

US3252553

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered '6 Apr 2021'	(b) (4), (b) (6)	07 Apr 2021 03:17:55

US3252553

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered '09:07'	(b) (4), (b) (6)	07 Apr 2021 03:17:55

US3252553

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
User entered '6 Apr 2021 09:07'	System	07 Apr 2021 03:17:55

US3252553

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered '98.3' F	(b) (4), (b) (6)	07 Apr 2021 03:17:55

US3252553

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered 'Oral (Oral)'	(b) (4), (b) (6)	07 Apr 2021 03:17:55

US3252553

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered empty.	(b) (4), (b) (6)	07 Apr 2021 03:17:55

US3252553

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered '60'	(b) (4), (b) (6)	07 Apr 2021 03:17:55

US3252553

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	07 Apr 2021 03:17:55

US3252553

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered '16'	(b) (4), (b) (6)	07 Apr 2021 03:17:55

US3252553

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	07 Apr 2021 03:17:55

US3252553

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered '115'	(b) (4), (b) (6)	07 Apr 2021 03:17:55

US3252553

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Apr 2021 03:17:55

US3252553

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered '69'	(b) (4), (b) (6)	07 Apr 2021 03:17:55

US3252553

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Apr 2021 03:17:55

US3252553

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	07 Apr 2021 03:18:33

US3252553

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Apr 2021 03:18:33

US3252553

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered '6 Apr 2021'	(b) (4), (b) (6)	07 Apr 2021 03:18:33

US3252553

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered '10:18'	(b) (4), (b) (6)	07 Apr 2021 03:18:33

US3252553

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
User entered '6 Apr 2021 10:18'	System	07 Apr 2021 03:18:33

US3252553

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered '98.0' F	(b) (4), (b) (6)	07 Apr 2021 03:18:33

US3252553

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered 'Oral (Oral)'	(b) (4), (b) (6)	07 Apr 2021 03:18:33

US3252553

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered empty.	(b) (4), (b) (6)	07 Apr 2021 03:18:33

US3252553

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered '61'	(b) (4), (b) (6)	07 Apr 2021 03:18:33

US3252553

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	07 Apr 2021 03:18:33

US3252553

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered '16'	(b) (4), (b) (6)	07 Apr 2021 03:18:33

US3252553

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	07 Apr 2021 03:18:33

US3252553

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered '123'	(b) (4), (b) (6)	07 Apr 2021 03:18:33

US3252553

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Apr 2021 03:18:33

US3252553

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered '65'	(b) (4), (b) (6)	07 Apr 2021 03:18:33

US3252553

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Apr 2021 03:18:33

US3252553

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:15:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered 'No (N)'	(b) (4), (b) (6)	07 Apr 2021 03:18:39

US3252553

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:15:52

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered empty.	(b) (4), (b) (6)	07 Apr 2021 03:18:39

US3252553

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Apr 2021 03:18:58

US3252553

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered empty.	(b) (4), (b) (6)	07 Apr 2021 03:18:58

US3252553

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered empty.	(b) (4), (b) (6)	07 Apr 2021 03:18:58

US3252553

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
User entered 'mRNA-1273'	System	07 Apr 2021 03:18:58
DataPoint set to visible.	System	15 Mar 2021 03:16:42

US3252553

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered '6 Apr 2021'	(b) (4), (b) (6)	07 Apr 2021 03:18:58

US3252553

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered '09:41'	(b) (4), (b) (6)	07 Apr 2021 03:18:58

US3252553

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
User entered '6 Apr 2021 09:41'	System	07 Apr 2021 03:18:58

US3252553

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	07 Apr 2021 03:18:58

US3252553

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered 'ONCE'	System	07 Apr 2021 03:18:58

US3252553

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	07 Apr 2021 03:18:58

US3252553

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Apr 2021 03:19:05

US3252553

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Apr 2021 03:19:05

US3252553

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:15:52

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:40:49
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:12:36
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 19:13:52
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	25 Sep 2020 08:10:07

US3252553

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:31:45
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:28:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 18:25:28
DataPoint Un-verified.		12 Mar 2021 16:20:42
User entered empty; reason for change Data Entry Error		12 Mar 2021 16:20:42
Un-reviewed for Safety.		12 Mar 2021 16:20:30
DataPoint activated with code reason code Data required.		18 Feb 2021 07:35:11
DataPoint inactivated with code reason code Data not required.		10 Feb 2021 07:58:22
DataPoint Verified.		03 Dec 2020 18:35:31
Reviewed for Safety.		28 Oct 2020 21:00:35
User entered 'USA-US108-2020-mRNA-1273-P301000011'	System	28 Oct 2020 21:00:29
User entered 'New'	(b) (4), (b) (6)	28 Oct 2020 21:00:29

US3252553

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:31:45
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:28:29
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Ankle fracture, LLT: Malleolar fracture - version MedDRA\23.0.	Coder Import (b) (4)	12 Mar 2021 13:20:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	12 Mar 2021 13:20:44
Data point term sent to Coder	System	11 Mar 2021 20:05:51
DataPoint Un-verified.	Xavier Morales (b) (4)	11 Mar 2021 20:05:34
Coding entries removed.	(b) (4)	11 Mar 2021 20:05:34
User entered 'Nondisplaced fracture of the lateral malleolus' reason for change: Data Entry Error	Xavier Morales (b) (4)	11 Mar 2021 20:05:34
User closed query 'PV Query: Please provide circumstances surrounding the event (i.e., how the fracture occurred).' (Site from Safety).	(b) (4)	04 Mar 2021 17:30:27
Query 'PV Query: Please provide circumstances surrounding the event (i.e., how the fracture occurred).' answered with 'No information was given by the subject' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 05:39:59
User opened query 'PV Query: Please provide circumstances surrounding the event (i.e., how the fracture occurred).' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 16:09:10
User closed query 'Per DM CLR: Please note this AE overlaps with AE #1. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 12:36:45
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Ankle fracture, LLT: Ankle fracture - version MedDRA\23.0.	Coder Import (b) (4)	18 Feb 2021 07:35:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	18 Feb 2021 07:35:56
Data point term sent to Coder	System	18 Feb 2021 07:35:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Feb 2021 07:35:11
Data point term sent to Coder	System	10 Feb 2021 07:58:30
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 07:58:22
Query 'Per DM CLR: Please note this AE overlaps with AE #1. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 07:55:31
User opened query 'Per DM CLR: Please note this AE overlaps with AE #1. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 02:02:20
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 18:35:41
User closed query 'PV Query: Please consider updating the event term to the final diagnosis (type and anatomical location of the fracture).' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 12:44:38
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Ankle fracture, LLT: Ankle fracture - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 22:13:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 22:13:57
Data point term sent to Coder	System	24 Nov 2020 22:12:22
Query 'PV Query: Please consider updating the event term to the final diagnosis (type and anatomical location of the fracture).' answered with 'updated' (Site from Safety).	Joanna Gurrola Mahoney (b) (4)	24 Nov 2020 22:11:41
Coding entries removed.	Joanna Gurrola Mahoney (b) (4)	24 Nov 2020 22:11:35
User entered 'Right ankle FRACTURE' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	24 Nov 2020 22:11:35
User opened query 'PV Query: Please consider updating the event term to the final diagnosis (type and anatomical location of the fracture).' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 13:51:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Fractures and dislocations NEC, PT: Fracture, LLT: Fracture - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 18:03:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 18:03:40
Data point term sent to Coder	System	28 Oct 2020 15:30:53
User entered 'Fracture'	Xavier Morales (b) (4)	28 Oct 2020 15:30:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:31:45
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Feb 2021 07:35:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 07:58:22
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:38:20
User entered 'Yes (Y)'	Xavier Morales (b) (4) (b) (4)	28 Oct 2020 15:30:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:31:45
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Feb 2021 07:35:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 07:58:22
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:38:23
User entered 'No (N)'	Xavier Morales (b) (4) (b) (4)	28 Oct 2020 15:30:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:31:45
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 15:56:47
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'test was not done. subject was not hospitalized after all for this he was seen at his ortho office.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 03:30:17
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 16:03:22
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Feb 2021 07:35:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 07:58:22
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:38:28
User entered 'No (N)'	Xavier Morales (b) (4)	28 Oct 2020 15:30:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:31:45
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:28:37
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
DataPoint Un-verified.	Xavier Morales (b) (4)	11 Mar 2021 14:13:06
	(b) (4)	
User entered '13 Oct 2020' reason for change: Data Entry Error	Xavier Morales (b) (4)	11 Mar 2021 14:13:06
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Feb 2021 07:35:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 07:58:22
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:38:32
User entered '23 Oct 2020'	Xavier Morales (b) (4)	28 Oct 2020 15:30:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:31:45
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Feb 2021 07:35:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 07:58:22
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 18:35:44
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4), (b) (6)	25 Nov 2020 13:57:02
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'this is the time in emr.' (Site from System).	Joanna Gurrola Mahoney (b) (4)	24 Nov 2020 22:08:44
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	24 Nov 2020 22:07:54
User entered '00:00' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	24 Nov 2020 22:07:54
User entered empty.	Xavier Morales (b) (4) (b) (4)	28 Oct 2020 15:30:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:31:45
User entered '13 Oct 2020 00:00'	System	11 Mar 2021 14:13:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Feb 2021 07:35:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 07:58:22
User entered '23 Oct 2020 00:00'	System	24 Nov 2020 22:07:54
User entered empty.	System	28 Oct 2020 15:30:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:31:45
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:28:40
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
DataPoint Un-verified.	Xavier Morales (b) (4)	11 Mar 2021 14:13:06
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Xavier Morales (b) (4)	11 Mar 2021 14:13:06
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Feb 2021 07:35:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 07:58:22
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 18:35:46
User entered 'Yes (Y)'	Xavier Morales (b) (4)	28 Oct 2020 15:30:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:31:45
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:28:44
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
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)	12 Mar 2021 15:57:04
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	12 Mar 2021 09:11:00
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'End date is 05-MAR-2021' (Site from System).	Xavier Morales (b) (4)	11 Mar 2021 20:05:16
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 'end date has been marked as 5-MAR-2021' (Site from Safety).	Xavier Morales (b) (4)	11 Mar 2021 20:04:57
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	11 Mar 2021 14:13:06
DataPoint Un-verified.	Xavier Morales (b) (4)	11 Mar 2021 14:13:06
User entered '5 Mar 2021' reason for change: Data Entry Error	Xavier Morales (b) (4)	11 Mar 2021 14:13:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Feb 2021 07:35:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 07:58:22
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:14:40
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)	06 Nov 2020 13:48:52
User entered empty.	Xavier Morales (b) (4)	28 Oct 2020 15:30:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:31:45
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Feb 2021 07:35:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 07:58:22
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:03:46
User entered empty.	Xavier Morales (b) (4) (b) (4)	28 Oct 2020 15:30:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:31:45
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Feb 2021 07:35:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 07:58:22
User entered empty.	System	28 Oct 2020 15:30:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:31:45
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
Query 'PV Query: Since the subject was hospitalized for the event of right ankle fracture, appropriate CTCAE grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain.' canceled (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 15:55:42
User opened query 'PV Query: Since the subject was hospitalized for the event of right ankle fracture, appropriate CTCAE grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:15:16
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Feb 2021 07:35:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 07:58:22
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:39:27
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Xavier Morales (b) (4) (b) (4)	28 Oct 2020 15:30:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:31:45
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:28:52
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	11 Mar 2021 20:05:34
DataPoint Un-verified.	Xavier Morales (b) (4)	11 Mar 2021 20:05:34
User entered 'No (N)' reason for change: Data Entry Error	Xavier Morales (b) (4)	11 Mar 2021 20:05:34
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	11 Mar 2021 14:13:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Feb 2021 07:35:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 07:58:22
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:39:39
User entered 'Yes (Y)'	Xavier Morales (b) (4)	28 Oct 2020 15:30:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:31:45
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Feb 2021 07:35:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 07:58:22
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:39:45
User entered '0'	Xavier Morales (b) (4)	28 Oct 2020 15:30:32
	(b) (4)	

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Form: Adverse Events (2)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:31:45
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Feb 2021 07:35:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 07:58:22
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:39:46
User entered '0'	Xavier Morales (b) (4)	28 Oct 2020 15:30:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:31:45
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:28:55
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		11 Mar 2021 14:13:06
Query 'Requires inpatient or prolongation of existing System Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		11 Mar 2021 14:13:06
DataPoint Un-verified.	Xavier Morales (b) (4)	11 Mar 2021 14:13:06
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Xavier Morales (b) (4)	11 Mar 2021 14:13:06
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	18 Feb 2021 07:35:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 07:58:22
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:39:48
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	28 Oct 2020 15:30:32
User entered '1'	Xavier Morales (b) (4)	28 Oct 2020 15:30:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:31:45
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:28:57
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Per CDM: Hospitalization is recorded, over no admission or discharge date is recorded. Please update. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 09:11:28
Query 'Per CDM: Hospitalization is recorded, over no admission or discharge date is recorded. Please update. ' answered with 'No hospitalization was recorded for this AE, was input by mistake as a result of verbal narrative the patients wife told us' (Site from DM).	Xavier Morales (b) (4)	11 Mar 2021 20:09:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Feb 2021 07:35:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 07:58:22
User opened query 'Per CDM: Hospitalization is recorded, over no admission or discharge date is recorded. Please update. ' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 15:12:29
User entered empty.	Xavier Morales (b) (4)	28 Oct 2020 15:30:32

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Folder: Adverse Events

Form: Adverse Events (2)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:31:45
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:28:59
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 15:57:18
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 15:57:13
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'No hospitalization was recorded for this AE, was input by mistake as a result of verbal narrative the patients wife told us' (Site from Safety).	Xavier Morales (b) (4) (b) (4)	11 Mar 2021 20:09:41
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'per query and per source, the documents are unable to obtain. thanks' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 03:34:29
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 16:12:28
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 16:03:53

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EAB) (1725)

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Feb 2021 07:35:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 07:58:22
User entered empty.	Xavier Morales (b) (4) (b) (4)	28 Oct 2020 15:30:32

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:31:45
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:29:02
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Feb 2021 07:35:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 07:58:22
User entered empty.	Xavier Morales (b) (4) (b) (4)	28 Oct 2020 15:30:32

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:31:45
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:29:03
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Feb 2021 07:35:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 07:58:22
User entered empty.	Xavier Morales (b) (4)	28 Oct 2020 15:30:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:31:45
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Feb 2021 07:35:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 07:58:22
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:43:11
User entered '0'	Xavier Morales (b) (4) (b) (4)	28 Oct 2020 15:30:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:31:45
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Feb 2021 07:35:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 07:58:22
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:43:13
User entered '0'	Xavier Morales (b) (4)	28 Oct 2020 15:30:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:31:45
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Feb 2021 07:35:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 07:58:22
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:43:15
User entered '0'	Xavier Morales (b) (4) (b) (4)	28 Oct 2020 15:30:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:31:45
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Feb 2021 07:35:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 07:58:22
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 18:43:24
User entered 'Not Related (NOT RELATED)'	Xavier Morales (b) (4) (b) (4)	28 Oct 2020 15:30:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:31:45
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Feb 2021 07:35:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 07:58:22
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:46:33
User entered 'Not Related (NOT RELATED)'	Xavier Morales (b) (4) (b) (4)	28 Oct 2020 15:30:32

US3252553

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:31:45
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:49:36
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:13:56
User closed query 'Hello, I have been unable to locate "dose delayed" as action taken with IP in source.The AE log "action taken with study medication" = not applicable. Please review. ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 16:13:54
Query 'Hello, I have been unable to locate "dose delayed" as action taken with IP in source.The AE log "action taken with study medication" = not applicable. Please review. ' answered with 'Updated to match source' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 15:09:57
Signature has been broken.	(b) (4), (b) (6)	26 Apr 2021 15:09:44
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error		26 Apr 2021 15:09:44
User opened query 'Hello, I have been unable to locate "dose delayed" as action taken with IP in source.The AE log "action taken with study medication" = not applicable. Please review. ' (Site from CRA).		26 Apr 2021 14:07:07
User closed query 'The dose delayed is noted in EDC, however it is not noted in source. Please note in source. ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 14:07:07
Query 'The dose delayed is noted in EDC, however it is not noted in source. Please note in source. ' answered with 'It's in source as well.' (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 22:01:43
User opened query 'The dose delayed is noted in EDC, however it is not noted in source. Please note in source. ' (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 17:35:17
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:32:02
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:30:21
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'PV Query: Please confirm action taken as the subject only received 1 dose of study drug prior to event onset.' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 15:57:22

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

Action taken with investigational product

Audit	User	Time (GMT)
Query 'PV Query: Please confirm action taken as the subject only received 1 dose of study drug prior to event onset.' answered with 'updated' (Site from Safety).	mathew maran (b) (4)	12 Mar 2021 04:49:12
User entered 'Dose Delayed (DOSE DELAYED)' reason for change: Data Entry Error	mathew maran (b) (4)	12 Mar 2021 04:49:05
User opened query 'PV Query: Please confirm action taken as the subject only received 1 dose of study drug prior to event onset.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 18:03:32
User closed query 'PV Query: Action taken with study drug still has not been updated. Action taken should be updated to Withdrawn if subject will not be receiving any further IP doses. Please update accordingly. Otherwise, please clarify.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 16:40:52
User closed query 'Action Taken with Investigational System Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).		26 Feb 2021 04:51:43
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	26 Feb 2021 04:51:43
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	mathew maran (b) (4)	26 Feb 2021 04:51:43
Query 'PV Query: Action taken with study drug still has not been updated. Action taken should be updated to Withdrawn if subject will not be receiving any further IP doses. Please update accordingly. Otherwise, please clarify.' answered with 'updated per query' (Site from Safety).	mathew maran (b) (4)	26 Feb 2021 04:50:32
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	26 Feb 2021 04:50:04
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	mathew maran (b) (4)	26 Feb 2021 04:50:04

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Folder: Adverse Events

Form: Adverse Events (2)

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Action taken with investigational product

Audit	User	Time (GMT)
User opened query 'PV Query: Action taken with study drug still has not been updated. Action taken should be updated to Withdrawn if subject will not be receiving any further IP doses. Please update accordingly. Otherwise, please clarify.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:16:28
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 20:02:19
User closed query 'Action Taken with Investigational System Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).		18 Feb 2021 07:39:23
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	18 Feb 2021 07:39:23
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 07:39:23
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 07:38:53
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	18 Feb 2021 07:38:20
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 07:38:20
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 07:38:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Feb 2021 07:35:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 07:58:22

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Folder: Adverse Events

Form: Adverse Events (2)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:20:54
DataPoint Un-verified.	(b) (4), (b) (6)	21 Nov 2020 00:47:42
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:46:45
	(b) (4), (b) (6)	21 Nov 2020 00:46:41
User entered 'Not Applicable (NOT APPLICABLE)'	Xavier Morales (b) (4) (b) (4)	28 Oct 2020 15:30:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:31:45
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 16:55:38
User closed query 'Per source concomitant medications and procedures are listed. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	23 Mar 2021 16:55:35
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 12:39:59
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given.' answered with 'medications updated' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 07:42:18
Query 'Per source concomitant medications and procedures are listed. Please verify and update EDC accordingly.' answered with 'EDC updated' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 07:42:10
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 07:41:22
DataPoint activated with code reason code Data required.		18 Feb 2021 07:35:11
DataPoint inactivated with code reason code Data not required.		10 Feb 2021 07:58:22
User opened query 'Per source concomitant medications and procedures are listed. Please verify and update EDC accordingly.' (Site from CRA).		27 Jan 2021 19:16:33

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Folder: Adverse Events

Form: Adverse Events (2)

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None

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 02:02:33
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	24 Nov 2020 16:08:43
User entered '1' reason for change: Data Entry Error	Joanna Gurrola Mahoney	24 Nov 2020 16:08:43
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	28 Oct 2020 15:30:32
User entered '0'	System	28 Oct 2020 15:30:32
	Xavier Morales (b) (4)	28 Oct 2020 15:30:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:31:45
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 16:55:39
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 07:41:22
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Feb 2021 07:35:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 07:58:22
User entered '0'	Xavier Morales (b) (4)	28 Oct 2020 15:30:32
	(b) (4)	

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Form: Adverse Events (2)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:31:45
User closed query 'Per source, concomitant procedures are listed. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 17:30:30
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:30:28
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
Query 'Per source, concomitant procedures are listed. Please verify and update EDC accordingly.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 07:34:55
User entered '1' reason for change: New Information	(b) (4), (b) (6)	24 Mar 2021 07:34:34
User opened query 'Per source, concomitant procedures are listed. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	23 Mar 2021 16:55:57
User closed query 'PV Query: Please provide any diagnostic or laboratory testing performed to diagnose or monitor the event, with dates performed.' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 16:00:14
Query 'PV Query: Please provide any diagnostic or laboratory testing performed to diagnose or monitor the event, with dates performed.' answered with 'medical records from ortho have no prescribed medications' (Site from Safety).	mathew maran (b) (4)	12 Mar 2021 04:51:46
User entered '0' reason for change: New Information	mathew maran (b) (4)	12 Mar 2021 04:51:37
User entered '1' reason for change: Data Entry Error	Xavier Morales (b) (4)	11 Mar 2021 20:36:59
User opened query 'PV Query: Please provide any diagnostic or laboratory testing performed to diagnose or monitor the event, with dates performed.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 16:05:50
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Feb 2021 07:35:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 07:58:22
User entered '0'	Xavier Morales (b) (4)	28 Oct 2020 15:30:32

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:31:45
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:30:37
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
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)	12 Mar 2021 16:00:24
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 'IT HAS BEEN RESOLVED WITH END DATE OF 05-MAR-2021' (Site from Safety).	Xavier Morales (b) (4)	11 Mar 2021 20:37:22
DataPoint Un-verified.	Xavier Morales (b) (4)	11 Mar 2021 20:36:59
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Xavier Morales (b) (4)	11 Mar 2021 20:36:59
Data Entry Error	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Feb 2021 07:35:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 07:58:22
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:17:21
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)	06 Nov 2020 13:49:03
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Xavier Morales (b) (4)	28 Oct 2020 15:30:32

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:31:45
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Feb 2021 07:35:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 07:58:22
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:17:23
User entered empty.	Xavier Morales (b) (4) (b) (4)	28 Oct 2020 15:30:32

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:31:45
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'PV query: Please clarify if dehydration or underlying reason for dehydration met AE/SAE reporting criteria.' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 16:18:44
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)	12 Mar 2021 16:00:29
Query 'PV query: Please clarify if dehydration or underlying reason for dehydration met AE/SAE reporting criteria.' answered with 'It was originally thought that the patient was hospitalized due to the fractures but once the medical records were obtained, was found out to be that the patient was not hospitalized for the fractures but for another AE. This AE has been added to source and EDC as a SAE. There are no dates in regards to the timeline of this SAE and medical records for the hospitalization will be requested from the hospital.' (Site from Safety).	mathew maran (b) (4) (b) (4)	12 Mar 2021 04:51:13
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 'It was originally thought that the patient was hospitalized due to the fractures but once the medical records were obtained, was found out to be that the patient was not hospitalized for the fractures but for another AE' (Site from Safety).	mathew maran (b) (4) (b) (4)	12 Mar 2021 04:50:31
Query 'PV Query: Please clarify date of IP administration. Both IP doses were reported with the same date (24 Sep 2020). Please consider updating the date (s) for the IP dose.' canceled (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 18:02:48

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV query: Please clarify if dehydration or underlying reason for dehydration met AE/SAE reporting criteria.' canceled (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 14:57:10
User opened query 'PV query: Please clarify if dehydration or underlying reason for dehydration met AE/SAE reporting criteria.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 16:10:03
User opened query 'PV Query: Please clarify date of IP administration. Both IP doses were reported with the same date (24 Sep 2020). Please consider updating the date (s) for the IP dose.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 16:07:33
User closed query 'PV Query: Please provide any diagnostic or laboratory testing performed to diagnose or monitor the event, with dates performed.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 16:40:59
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 16:40:56
User closed query 'Per DM CLR: Dehydration is noted in the SAE Narrative. Please update to include in AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 11:14:21
Query 'Per DM CLR: Dehydration is noted in the SAE Narrative. Please update to include in AE eCRF as appropriate.' answered with 'there is no further documents available as the patient is no longer part of the study' (Site from DM).	mathew maran (b) (4)	26 Feb 2021 04:55:15
Query 'PV Query: Please provide any diagnostic or laboratory testing performed to diagnose or monitor the event, with dates performed.' answered with 'no documents available. patient is no longer in the study. lost to follow up' (Site from Safety).	mathew maran (b) (4)	26 Feb 2021 04:53:37
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'no documents available. patient is no longer in the study' (Site from Safety).	mathew maran (b) (4)	26 Feb 2021 04:52:53
User closed query 'PV Query: Please provide circumstances surrounding the event (i.e., how the fracture occurred).' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 20:02:37

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Thank you for confirming that the non-serious event (AE #1) and this serious event are the same. As such, please combine the information from the non-serious event with this event (the non-serious event can then be deleted from the EDC). ' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 20:02:29
Query 'PV Query: Please provide circumstances surrounding the event (i.e., how the fracture occurred).' answered with 'no data available for now' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 07:46:57
Query 'PV Query: Thank you for confirming that the non-serious event (AE #1) and this serious event are the same. As such, please combine the information from the non-serious event with this event (the non-serious event can then be deleted from the EDC).' ' answered with 'done' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 07:43:26
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Feb 2021 07:35:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 07:58:22
User opened query 'PV Query: Thank you for confirming that the non-serious event (AE #1) and this serious event are the same. As such, please combine the information from the non-serious event with this event (the non-serious event can then be deleted from the EDC).' ' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 21:19:01
Query 'Thank you for confirming that the non-serious event (AE #1) and this serious event are the same. As such, please combine the information from the non-serious event with this event (the non-serious event can then be deleted from the EDC).'	(b) (4), (b) (6)	05 Feb 2021 21:18:55
Query 'Thank you for confirming that the non-serious event (AE #1) and this serious event are the same. As such, please combine the information from the non-serious event with this event (the non-serious event can then be deleted from the EDC).'	(b) (4), (b) (6)	05 Feb 2021 21:18:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV query: Please clarify if the reported event is the same fracture from the previous AE that was reported on 13 Oct 2020, if so please combine this event into previously reported AE and capture as an SAE as applicable. Else clarify.' canceled (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 21:18:46
User opened query 'Per DM CLR: Dehydration is noted in the SAE Narrative. Please update to include in AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 18:34:22
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 18:44:06
User closed query 'PV Query: Please clarify date of IP administration. Both IP doses were reported with the same date (24 Sep 2020). Please consider updating the date (s) for the IP dose.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 12:44:52
Query 'PV Query: Please clarify date of IP administration. Both IP doses were reported with the same date (24 Sep 2020). Please consider updating the date (s) for the IP dose.' answered with 'Subject did not make it for Day 29's dose as he was hospitalized. We are unable to reach him still. So the subject only received one IP dose at Day 1 on 24 Sep 2020' (Site from Safety).	Joanna Gurrola Mahoney (b) (4)	24 Nov 2020 21:42:11
User opened query 'PV Query: Please provide circumstances surrounding the event (i.e., how the fracture occurred).' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 13:51:20
User opened query 'PV query: Please clarify if dehydration or underlying reason for dehydration met AE/SAE reporting criteria.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 13:51:16
User opened query 'PV query: Please clarify if the reported event is the same fracture from the previous AE that was reported on 13 Oct 2020, if so please combine this event into previously reported AE and capture as an SAE as applicable. Else clarify.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 13:50:46
User opened query 'PV Query: Please clarify date of IP administration. Both IP doses were reported with the same date (24 Sep 2020). Please consider updating the date (s) for the IP dose.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 13:50:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[Narrative](#)

Audit	User	Time (GMT)
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)	06 Nov 2020 13:50:24
User opened query 'PV Query: Please provide any diagnostic or laboratory testing performed to diagnose or monitor the event, with dates performed.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 13:50:18
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 13:49:19
User entered 'PARTICIPANTS WIFE CALLED IN TODAY, 24-OCT-2020, NOTIFYING US THAT HER HUSBAND HAS BEEN HOSPITALIZED FOR A FRACTURE AND DEHYDRATION. IT IS UNSURE AT THIS TIME IF IT IS THE SAME FRACTURE FROM THE PREVIOUS AE THAT WAS REPORTED ON 13-OCT-2020. DETAILS WILL BE UPDATED ONCE MEDICAL RECORDS ARE OBTAINED.'	Xavier Morales (b) (4) (b) (4)	28 Oct 2020 15:30:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:31:45
User entered '0'	System	11 Mar 2021 20:05:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Feb 2021 07:35:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 07:58:22
User entered '1'	System	28 Oct 2020 15:30:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:31:45
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Feb 2021 07:35:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 07:58:22
User entered 'I'	System	28 Oct 2020 15:30:32

US3252553

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:31:45
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Feb 2021 07:35:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 07:58:22

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:15:52

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:52

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:15:52

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:52
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:31:02
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Wrist fracture, LLT: Fractured scaphoid - version MedDRA\\23.0.	Coder Import (b) (4)	12 Mar 2021 13:19:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	(b) (4)	12 Mar 2021 13:19:44
Data point term sent to Coder	System	11 Mar 2021 20:03:47
User entered 'Nondisplaced fracture of the right scaphoid'	Xavier Morales (b) (4)	11 Mar 2021 20:02:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:15:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:52
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:31:10
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered 'Yes (Y)'	Xavier Morales (b) (4)	11 Mar 2021 20:02:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:15:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:52
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:31:18
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered 'No (N)'	Xavier Morales (b) (4)	11 Mar 2021 20:02:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:15:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:52
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:31:22
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered 'No (N)'	Xavier Morales (b) (4)	11 Mar 2021 20:02:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:15:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:52
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:31:24
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '13 Oct 2020'	Xavier Morales (b) (4)	11 Mar 2021 20:02:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:15:52

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:52
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:31:26
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	11 Mar 2021 20:02:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:15:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:52
User entered empty.	System	11 Mar 2021 20:02:52

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:15:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:52
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:31:27
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered 'No (N)'	Xavier Morales (b) (4)	11 Mar 2021 20:02:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:15:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:52
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:31:29
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '5 Mar 2021'	Xavier Morales (b) (4)	11 Mar 2021 20:02:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:15:52

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:52
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:31:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	11 Mar 2021 20:02:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:15:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:52
User entered empty.	System	11 Mar 2021 20:02:52

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:15:52

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:52
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:31:33
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered 'Grade 1/Mild (Grade 1/Mild)'	Xavier Morales (b) (4)	11 Mar 2021 20:02:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:15:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:52
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:31:34
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered 'No (N)'	Xavier Morales (b) (4)	11 Mar 2021 20:02:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:15:52

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:52
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	11 Mar 2021 20:02:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:15:52

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:52
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	11 Mar 2021 20:02:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:15:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:52
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	11 Mar 2021 20:02:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:15:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:52
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	11 Mar 2021 20:02:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:15:52

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:52
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	11 Mar 2021 20:02:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:15:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:52
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	11 Mar 2021 20:02:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:15:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:52
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	11 Mar 2021 20:02:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:15:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:52
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	11 Mar 2021 20:02:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:15:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:52
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	11 Mar 2021 20:02:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:52
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	11 Mar 2021 20:02:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:15:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:52
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:31:45
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered 'Not Related (NOT RELATED)'	Xavier Morales (b) (4)	11 Mar 2021 20:02:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:15:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:52
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered 'Not Related (NOT RELATED)'	Xavier Morales (b) (4)	11 Mar 2021 20:02:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:15:52

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:52
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered 'None (NONE)'	Xavier Morales (b) (4)	11 Mar 2021 20:02:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:15:52

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:52
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	11 Mar 2021 20:02:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:15:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:52
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered 'I'	Xavier Morales (b) (4)	11 Mar 2021 20:02:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:15:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:52
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	11 Mar 2021 20:02:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:15:52

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:52
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Xavier Morales (b) (4) (b) (4)	11 Mar 2021 20:02:52

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:15:52

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:52
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	11 Mar 2021 20:02:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:15:52

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:52
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	11 Mar 2021 20:02:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:15:52

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:52
User entered '0'	System	11 Mar 2021 20:02:52

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:15:52

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:52
User entered '1'	System	11 Mar 2021 20:02:52

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:15:52

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:52

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:15:52

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 18:25:28
User entered	(b) (4), (b) (6)	12 Mar 2021 16:25:42
'USA-US108-2020-mRNA-1273-P301000011'		

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:15:52

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis acute, LLT: Acute cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4)	11 Mar 2021 21:44:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Mar 2021 21:44:57
Data point term sent to Coder	System	11 Mar 2021 21:44:41
User entered 'Acute Cholecystitis'	Xavier Morales (b) (4)	11 Mar 2021 21:44:24

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:15:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered 'Yes (Y)'	Xavier Morales (b) (4)	11 Mar 2021 21:44:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:15:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered 'No (N)'	Xavier Morales (b) (4)	11 Mar 2021 21:44:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:15:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered 'No (N)'	Xavier Morales (b) (4)	11 Mar 2021 21:44:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:15:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Mar 2021 20:26:07
User entered '23 Oct 2020' reason for change: Data Entry Error	Xavier Morales (b) (4)	12 Mar 2021 20:26:07
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Mar 2021 21:44:24
User entered '00 0000' (non-conformant).	Xavier Morales (b) (4)	11 Mar 2021 21:44:24

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	11 Mar 2021 21:44:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Mar 2021 21:44:24

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Folder: Adverse Events

Form: Adverse Events (4)

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered 'No (N)'	Xavier Morales (b) (4)	11 Mar 2021 21:44:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Mar 2021 20:26:07
User entered '4 Nov 2020' reason for change: Data Entry Error	Xavier Morales (b) (4)	12 Mar 2021 20:26:07
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Mar 2021 21:44:24
User entered '00 0000' (non-conformant).	Xavier Morales (b) (4)	11 Mar 2021 21:44:24

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Folder: Adverse Events

Form: Adverse Events (4)

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End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	11 Mar 2021 21:44:24
	(b) (4)	

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Folder: Adverse Events

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Mar 2021 21:44:24

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:15:52

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered 'Grade 3/Severe (Grade 3/Severe)'	Xavier Morales (b) (4)	11 Mar 2021 21:44:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:15:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible. ' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 16:21:40
Query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible. ' answered with 'updated, MEDICAL RECORDS FOR THIS SAE ARE PENDING AND WILL BE UPDATED WITH DATES AND MEDICATIONS ONCE ARE AVAILABLE.' (Site from Safety).	mathew maran (b) (4) (b) (4)	12 Mar 2021 04:58:42
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	12 Mar 2021 04:58:21
User opened query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible. ' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 23:08:09
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	11 Mar 2021 21:44:24
User entered 'Yes (Y)'	Xavier Morales (b) (4) (b) (4)	11 Mar 2021 21:44:24

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:15:52

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	11 Mar 2021 21:44:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:15:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	11 Mar 2021 21:44:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:15:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	15 Mar 2021 13:23:07
User closed query 'Per CDM: Response noted, However Please update the data once it is available. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 13:22:59
Query 'Per CDM: Response noted, However Please update the data once it is available. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 02:59:56
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Subject was Hospitalized (pending medical records)' (Site from System).	(b) (4), (b) (6)	15 Mar 2021 02:59:36
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	12 Mar 2021 20:27:32
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	12 Mar 2021 16:11:41
User opened query 'Per CDM: Response noted, However Please update the data once it is available. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 16:11:33
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'MEDICAL RECORDS FOR THIS SAE ARE PENDING AND WILL BE UPDATED WITH DATES AND MEDICATIONS ONCE ARE AVAILABLE.' (Site from System).	mathew maran (b) (4) (b) (4)	12 Mar 2021 04:58:34

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:15:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	12 Mar 2021 04:58:21
User entered '1' reason for change: New Information	mathew maran (b) (4)	12 Mar 2021 04:58:21
User entered '0'	(b) (4) Xavier Morales (b) (4) (b) (4)	11 Mar 2021 21:44:24

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '23 Oct 2020' reason for change: Data Entry Error	Xavier Morales (b) (4)	12 Mar 2021 20:27:32
User entered empty.	Xavier Morales (b) (4)	11 Mar 2021 21:44:24

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Form: Adverse Events (4)

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[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '4 Nov 2020' reason for change: Data Entry Error	Xavier Morales (b) (4)	12 Mar 2021 20:27:32
User entered empty.	Xavier Morales (b) (4)	11 Mar 2021 21:44:24

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Folder: Adverse Events

Form: Adverse Events (4)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Per CDM: Requires inpatient or prolongation of existing Hospitalization is checked, however Admitted to ICU? is missing. Please review and updated accordingly. Else clarify.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 09:17:29
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Mar 2021 07:39:17
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	18 Mar 2021 07:38:58
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		18 Mar 2021 07:38:58
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Mar 2021 07:38:58
Query 'Per CDM: Requires inpatient or prolongation of existing Hospitalization is checked, however Admitted to ICU? is missing. Please review and updated accordingly. Else clarify.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 07:38:36
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	18 Mar 2021 07:38:11
User entered 'Unknown (UNK)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Mar 2021 07:38:11
User opened query 'Per CDM: Requires inpatient or prolongation of existing Hospitalization is checked, however Admitted to ICU? is missing. Please review and updated accordingly. Else clarify.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 13:24:13
User entered empty.	Xavier Morales (b) (4) (b) (4)	11 Mar 2021 21:44:24

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Admitted to ICU? is Yes, however System Number of Days in ICU is missing. Please review and reconcile.' (Site from System).		18 Mar 2021 07:39:17
Query 'Admitted to ICU? is Yes, however Number of System Days in ICU is missing. Please review and reconcile.' answered by data change (Site from System).		18 Mar 2021 07:39:17
User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	18 Mar 2021 07:38:58
User entered empty.	Xavier Morales (b) (4)	11 Mar 2021 21:44:24

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Folder: Adverse Events

Form: Adverse Events (4)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	11 Mar 2021 21:44:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	11 Mar 2021 21:44:24
	(b) (4)	

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Form: Adverse Events (4)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	11 Mar 2021 21:44:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
Query 'PV Query: Per unblinding form the subject was randomized to mRNA-1273 but Actual Dose 1 was reported as Placebo. Please reconcile, else clarify. ' canceled (Site from Safety).	(b) (6)	23 Mar 2021 15:13:47
User opened query 'PV Query: Per unblinding form the subject was randomized to mRNA-1273 but Actual Dose 1 was reported as Placebo. Please reconcile, else clarify. ' (Site from Safety).	(b) (6)	19 Mar 2021 04:38:10
User entered 'Not Related (NOT RELATED)'	Xavier Morales (b) (4)	11 Mar 2021 21:44:24

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Folder: Adverse Events

Form: Adverse Events (4)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered 'Not Related (NOT RELATED)'	Xavier Morales (b) (4)	11 Mar 2021 21:44:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'PV Query: Please confirm action taken as it is reported as 'dose delayed' for event, acute cholecystitis and 'withdrawn' for event, septic shock.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 14:07:05
Query 'PV Query: Please confirm action taken as it is reported as 'dose delayed' for event, acute cholecystitis and 'withdrawn' for event, septic shock.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 06:09:54
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 06:09:39
User opened query 'PV Query: Please confirm action taken as it is reported as 'dose delayed' for event, acute cholecystitis and 'withdrawn' for event, septic shock.' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 16:18:25
User closed query 'PV Query: Please confirm action taken as it is reported as 'dose delayed' for event, acute cholecystitis and 'withdrawn' for event, septic shock.' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 13:32:36
User entered 'Dose Delayed (DOSE DELAYED)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 10:25:29
Query 'PV Query: Please confirm action taken as it is reported as 'dose delayed' for event, acute cholecystitis and 'withdrawn' for event, septic shock.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 10:22:57
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 10:22:50
User opened query 'PV Query: Please confirm action taken as it is reported as 'dose delayed' for event, acute cholecystitis and 'withdrawn' for event, septic shock.' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 22:12:22
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Mar 2021 04:57:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Mar 2021 04:57:51
User entered 'Dose Delayed (DOSE DELAYED)' reason for change: Data Entry Error	mathew maran (b) (4)	12 Mar 2021 04:57:51
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Mar 2021 23:25:50

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Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Action Taken with Investigational System Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).		11 Mar 2021 23:25:50
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	11 Mar 2021 23:25:50
User entered empty; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	11 Mar 2021 23:25:50
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Mar 2021 23:24:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Mar 2021 23:24:46
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	11 Mar 2021 23:24:46
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	11 Mar 2021 23:24:46
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Mar 2021 21:44:24
User entered empty.	Xavier Morales (b) (4) (b) (4)	11 Mar 2021 21:44:24

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None

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	11 Mar 2021 21:44:24
	(b) (4)	

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Folder: Adverse Events

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:32:07
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' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 13:38:12
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'updated in CM form' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 04:17:12
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' answered with 'updated in conmed form' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 04:15:59
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 06:20:29
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' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 22:12:48
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' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 18:25:47

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[Concomitant Medication](#)

Audit	User	Time (GMT)
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 ' answered with 'updated' (Site from Safety). User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 07:37:42
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 ' (Site from Safety). User entered '0'	(b) (4), (b) (6)	19 Mar 2021 04:34:27
	Xavier Morales (b) (4)	11 Mar 2021 21:44:24
	(b) (4)	

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Per DM CLR RQ: Previous response noted.However there is no record of concomitant procedure within the timeframe of this Adverse event.Please review and update the details as accordingly,else clarify.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 14:44:15
Query 'Per DM CLR RQ: Previous response noted.However there is no record of concomitant procedure within the timeframe of this Adverse event.Please review and update the details as accordingly,else clarify.' answered with 'procedures are updated, thanks' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 07:10:22
User opened query 'Per DM CLR RQ: Previous response noted.However there is no record of concomitant procedure within the timeframe of this Adverse event.Please review and update the details as accordingly,else clarify.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:22:49
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:22:49
Query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 04:17:47
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 06:20:24
Query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure record was noted as a Diagnostic procedure rather than therapeutic. Please review and update to record the treatment procedure for this AE as applicable. Otherwise, clarify.' canceled (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 19:25:50

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure record was noted as a Diagnostic procedure rather than therapeutic. Please review and update to record the treatment procedure for this AE as applicable. Otherwise, clarify.' (Site from DM). User entered '1'	(b) (4), (b) (6)	22 Mar 2021 12:17:13
	Xavier Morales (b) (4)	11 Mar 2021 21:44:24
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Xavier Morales (b) (4) (b) (4)	11 Mar 2021 21:44:24

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	11 Mar 2021 21:44:24
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 14:10:18
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' answered with 'this was all that was provided to us and medical records are uploaded with no mention of COVID-19 testing' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 02:22:56
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' canceled (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 20:03:09
Query 'PV Query: Please provide any diagnostic or laboratory testing performed to diagnose or monitor the event, with dates performed. ' canceled (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 20:03:05
User closed query 'PV query: Please clarify if dehydration or underlying reason for dehydration met AE/SAE reporting criteria. ' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 12:46:23
Query 'PV query: Please clarify if dehydration or underlying reason for dehydration met AE/SAE reporting criteria. ' answered with 'there is no dehydration AE/SAE ' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 06:38:04
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' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 16:19:01
User opened query 'PV Query: Please provide any diagnostic or laboratory testing performed to diagnose or monitor the event, with dates performed. ' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 04:36:06

US3252553

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:15:52

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 04:35:45
User opened query 'PV query: Please clarify if dehydration or underlying reason for dehydration met AE/SAE reporting criteria. ' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 04:34:06
User entered 'While obtaining medical records for the Xavier Morales other AE's, fractures, it was seen that patient was seen for cholecystitis and was hospitalized for this. Medical records for this SAE are pending and will be updated with dates and medications once are available.'	(b) (4)	11 Mar 2021 21:44:24

US3252553

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:15:52

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Mar 2021 21:44:24

US3252553

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:15:52

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Mar 2021 21:44:24

US3252553

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:15:52

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Mar 2021 07:39:17
User entered '1'	System	18 Mar 2021 07:38:58
User entered '0'	System	18 Mar 2021 07:38:11

US3252553

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:15:52

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 18:25:28
User entered	(b) (4), (b) (6)	24 Mar 2021 18:25:23
'USA-US108-2020-mRNA-1273-P301000011'		

US3252553

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:15:52

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Sepsis, bacteraemia, viraemia and fungaemia NEC, PT: Septic shock, LLT: Septic shock - version MedDRA\\23.0.	Coder Import (b) (4)	22 Mar 2021 19:52:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Mar 2021 19:52:50
Data point term sent to Coder	System	22 Mar 2021 19:52:03
User entered 'Septic Shock'	Xavier Morales (b) (4)	22 Mar 2021 19:51:11

US3252553

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:15:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 18:41:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Mar 2021 18:41:36
User entered 'Yes (Y)' reason for change: Data Entry Error	Xavier Morales (b) (4)	23 Mar 2021 18:41:36
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:51:11
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:51:11

US3252553

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:15:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 18:41:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Mar 2021 18:41:36
User entered 'No (N)' reason for change: Data Entry Error	Xavier Morales (b) (4)	23 Mar 2021 18:41:36
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:51:11
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:51:11

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:15:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 18:41:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Mar 2021 18:41:36
User entered 'No (N)' reason for change: Data Entry Error	Xavier Morales (b) (4)	23 Mar 2021 18:41:36
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:51:11
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:51:11

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:15:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 18:41:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Mar 2021 18:41:36
User entered '23 Oct 2020' reason for change: Data Entry Error	Xavier Morales (b) (4)	23 Mar 2021 18:41:36
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:51:11
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:51:11

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:51:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:15:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Mar 2021 19:51:11

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:15:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 18:41:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Mar 2021 18:41:36
User entered 'No (N)' reason for change: Data Entry Error	Xavier Morales (b) (4)	23 Mar 2021 18:41:36
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:51:11
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:51:11

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:15:52

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '4 Nov 2020' reason for change: Data Entry Error	Xavier Morales (b) (4)	23 Mar 2021 18:41:36
User entered empty.	(b) (4)	
	Xavier Morales (b) (4)	22 Mar 2021 19:51:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:51:11
	(b) (4)	

US3252553

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:15:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Mar 2021 19:51:11

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:15:52

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 18:41:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Mar 2021 18:41:36
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Xavier Morales (b) (4)	23 Mar 2021 18:41:36
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:51:11
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:51:11

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:15:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Is the adverse event serious is No, System but seriousness criteria is provided. Please correct.' (Site from System).		23 Mar 2021 18:44:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Xavier Morales (b) (4)	23 Mar 2021 18:44:10
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 18:41:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Mar 2021 18:41:36
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	23 Mar 2021 18:41:36
User entered 'No (N)' reason for change: Data Entry Error	Xavier Morales (b) (4)	23 Mar 2021 18:41:36
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:51:11
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:51:11

US3252553

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:15:52

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:51:11
	(b) (4)	

US3252553

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:15:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '1' reason for change: Data Entry Error	Xavier Morales (b) (4)	23 Mar 2021 18:41:36
User entered '0'	(b) (4)	
	Xavier Morales (b) (4)	22 Mar 2021 19:51:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:15:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '1' reason for change: Data Entry Error	Xavier Morales (b) (4)	23 Mar 2021 18:41:36
User entered '0'	(b) (4)	
	Xavier Morales (b) (4)	22 Mar 2021 19:51:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:15:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '23 Oct 2020' reason for change: Data Entry Error	Xavier Morales (b) (4)	23 Mar 2021 18:41:36
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:51:11

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:15:52

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '4 Nov 2020' reason for change: Data Entry Error	Xavier Morales (b) (4)	23 Mar 2021 18:41:36
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:51:11

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:15:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Xavier Morales (b) (4)	23 Mar 2021 18:41:36
User entered empty.	(b) (4)	
	Xavier Morales (b) (4)	22 Mar 2021 19:51:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:15:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '12' reason for change: Data Entry Error	Xavier Morales (b) (4)	23 Mar 2021 18:41:36
User entered empty.	(b) (4)	
	Xavier Morales (b) (4)	22 Mar 2021 19:51:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:15:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:51:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:15:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:51:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:15:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:51:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:15:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 18:41:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Mar 2021 18:41:36
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Xavier Morales (b) (4)	23 Mar 2021 18:41:36
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:51:11
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:51:11

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:15:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 18:41:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Mar 2021 18:41:36
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Xavier Morales (b) (4)	23 Mar 2021 18:41:36
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:51:11
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:51:11

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:15:52

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'PV Query: Thank you for your recent response but this still has not been addressed. Please confirm action taken as it is reported as 'dose delayed' for acute cholecystitis and 'withdrawn' for septic shock. ' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 17:54:23
Query 'PV Query: Thank you for your recent response but this still has not been addressed. Please confirm action taken as it is reported as 'dose delayed' for acute cholecystitis and 'withdrawn' for septic shock. ' answered with 'updated' (Site from Safety).	Joanna Gurrola Mahoney (b) (4)	21 Apr 2021 22:19:34
User opened query 'PV Query: Thank you for your recent response but this still has not been addressed. Please confirm action taken as it is reported as 'dose delayed' for acute cholecystitis and 'withdrawn' for septic shock. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 20:04:02
User closed query 'Per CDM: Response noted, however Dosing Discontinuation is recorded as 'Lost to Follow Up'. Kindly review and update else clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 10:01:25
Query 'Per CDM: Response noted, however Dosing Discontinuation is recorded as 'Lost to Follow Up'. Kindly review and update else clarify. ' answered with 'the dosing discontinuation form is updated' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 08:45:22
User opened query 'Per CDM: Response noted, however Dosing Discontinuation is recorded as 'Lost to Follow Up'. Kindly review and update else clarify. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 01:13:22
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 Mar 2021 01:12:41
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 'yes it is a SAE' (Site from System).	Xavier Morales (b) (4)	23 Mar 2021 18:44:25
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 18:41:36

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:15:52

Action taken with investigational product

Audit	User	Time (GMT)
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Mar 2021 18:41:36
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	23 Mar 2021 18:41:36
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Xavier Morales (b) (4) (b) (4)	23 Mar 2021 18:41:36
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:51:11
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:51:11

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:15:52

None

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	31 Mar 2021 08:29:58
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:29:58
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	22 Mar 2021 19:51:11
User entered '0'	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:51:11

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:15:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:51:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:15:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:51:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:15:52

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 18:41:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Mar 2021 18:41:36
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Xavier Morales (b) (4)	23 Mar 2021 18:41:36
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:51:11
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:51:11

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:15:52

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:51:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:15:52

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'PV Query: Per medical records dated 10 Feb 2021, subject previously had open heart surgery for an aortic aneurysm. Please confirm if this should be reported as a separate AE/SAE. ' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 13:02:41
Query 'PV Query: Per medical records dated 10 Feb 2021, subject previously had open heart surgery for an aortic aneurysm. Please confirm if this should be reported as a separate AE/SAE. ' answered with 'Based on hospitalization records from hospital there were no further records only for the ones we added as AE's' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 02:53:28
User opened query 'PV Query: Per medical records dated 10 Feb 2021, subject previously had open heart surgery for an aortic aneurysm. Please confirm if this should be reported as a separate AE/SAE. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 20:04:24
User entered 'THE ADVERSE EVENT STARTED AND HOSPITALIZED ON 23 OCT 2020 AND ENDED ON 04 NOV 2020. PI FOUND THIS IS AS SAE. THE SUBJECT SHIFTED TO ICU ON 24 OCT 2020 and discharged on 04 nov 2020. ACCORDING TO PI, THE INTENSITY WAS SEVERE/GRADE 3, THE RELATIONSHIP TO INVESTIGATIONAL PRODUCT IS NOT RELATED AND NO ACTION TAKEN.' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:44:48
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	31 Mar 2021 08:42:55
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	31 Mar 2021 08:42:55
User entered 'the adverse event started and hospitalized on 23 oct 2020 and ended on 04 nov 2020. PI found this is as SAE. the subject shifted to ICU on 24 Oct 2020. According to PI, the intensity was severe/grade 3, the relationship to investigational product is not related and no action taken.' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:42:55

US3252553

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:15:52

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	23 Mar 2021 18:44:10
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:51:11

US3252553

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:15:52

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 18:44:10
User entered '0'	System	23 Mar 2021 18:41:36

US3252553

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:15:52

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Mar 2021 18:41:36

US3252553

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:15:52

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Mar 2021 18:41:36

US3252553

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:15:52

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:41:57

US3252553

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:15:52

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:41:57
User closed query 'Per MM: Please confirm the action taken with IP. 2) Please confirm this event does not meet seriousness criteria. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 09:58:57
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
Query 'Per MM: Please confirm the action taken with IP. 2) Please confirm this event does not meet seriousness criteria. ' answered with 'as per PI not an SAE.' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	21 Apr 2021 22:21:44
User opened query 'Per MM: Please confirm the action taken with IP. 2) Please confirm this event does not meet seriousness criteria. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 12:54:24
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Cholelithiasis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Mar 2021 19:52:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Mar 2021 19:52:51
Data point term sent to Coder	System	22 Mar 2021 19:52:03
User entered 'Cholelithiasis'	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:51:48

US3252553

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:15:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:41:57
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:28:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:28:13
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:28:13
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:51:48
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:51:48

US3252553

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:15:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:41:57
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:28:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:28:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:28:13
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:51:48
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:51:48

US3252553

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:15:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:41:57
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:28:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:28:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:28:13
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:51:48
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:51:48

US3252553

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:15:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:41:57
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:28:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:28:13
User entered '23 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:28:13
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:51:48
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:51:48

US3252553

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:41:57
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:51:48
	(b) (4)	

US3252553

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:15:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:41:57
User entered empty.	System	22 Mar 2021 19:51:48

US3252553

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:15:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:41:57
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:28:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:28:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:28:13
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:51:48
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:51:48

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:15:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:41:57
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '04 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:28:13
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:51:48
	(b) (4)	

US3252553

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:41:57
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:51:48
	(b) (4)	

US3252553

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:15:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:41:57
User entered empty.	System	22 Mar 2021 19:51:48

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:15:52

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:41:57
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:28:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:28:13
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:28:13
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:51:48
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:51:48

US3252553

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:15:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:41:57
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:28:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:28:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:28:13
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:51:48
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:51:48

US3252553

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:15:52

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:41:57
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:51:48
	(b) (4)	

US3252553

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:15:52

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:41:57
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:51:48
	(b) (4)	

US3252553

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:15:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:41:57
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:51:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:15:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:41:57
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:51:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:15:52

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:41:57
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:51:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:15:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:41:57
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:51:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:15:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:41:57
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:51:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:15:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:41:57
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:51:48
	(b) (4)	

US3252553

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:15:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:41:57
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:51:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:15:52

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:41:57
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:51:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:15:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:41:57
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:28:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:28:13
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:28:13
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:51:48
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:51:48

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:15:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:41:57
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:28:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:28:13
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:28:13
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:51:48
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:51:48

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:15:52

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:41:57
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:28:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:28:13
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:28:13
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:51:48
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:51:48

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:15:52

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:41:57
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	31 Mar 2021 08:28:13
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:28:13
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	22 Mar 2021 19:51:48
User entered '0'	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:51:48

US3252553

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:15:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:41:57
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:51:48
	(b) (4)	

US3252553

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:15:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:41:57
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:51:48
	(b) (4)	

US3252553

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:15:52

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:41:57
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:28:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:28:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:28:13
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:51:48
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:51:48

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:15:52

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:41:57
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:51:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:15:52

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:41:57
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:51:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:15:52

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:41:57
User entered '0'	System	31 Mar 2021 08:28:13

US3252553

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:15:52

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:41:57
User entered 'I'	System	31 Mar 2021 08:28:13

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:15:52

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:41:57

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:15:52

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:10

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:15:52

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:10
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Escherichia infections, PT: Escherichia bacteraemia, LLT: Escherichia coli bacteremia - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 10:32:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 10:32:31
Data point term sent to Coder	System	22 Mar 2021 19:53:05
User entered 'Escherichia Coli Bactermia'	Xavier Morales (b) (4)	22 Mar 2021 19:52:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:15:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:10
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:26:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:26:38
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:26:38
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:52:16
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:52:16

US3252553

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:15:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:10
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:26:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:26:38
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:26:38
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:52:16
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:52:16

US3252553

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:15:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:10
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:26:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:26:38
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:26:38
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:52:16
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:52:16

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:15:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:10
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:26:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:26:38
User entered '23 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:26:38
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:52:16
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:52:16

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:10
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:52:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:15:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:10
User entered empty.	System	22 Mar 2021 19:52:16

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:15:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:10
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:26:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:26:38
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:26:38
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:52:16
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:52:16

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:15:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:10
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '04 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:26:38
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:52:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:15:52

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:10
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:52:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:15:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:10
User entered empty.	System	22 Mar 2021 19:52:16

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:15:52

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:10
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:26:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:26:38
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:26:38
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:52:16
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:52:16

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:15:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:10
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:26:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:26:38
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:26:38
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:52:16
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:52:16

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:15:52

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:10
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:52:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:15:52

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:10
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:52:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:15:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:10
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:52:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:15:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:10
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:52:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:15:52

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:10
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:52:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:15:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:10
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:52:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:10
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:52:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:15:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:10
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:52:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:15:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:10
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:52:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:15:52

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:10
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:52:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:15:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:10
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:26:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:26:38
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:26:38
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:52:16
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:52:16

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:15:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:10
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:26:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:26:38
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:26:38
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:52:16
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:52:16

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:15:52

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:10
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:26:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:26:38
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:26:38
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:52:16
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:52:16

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:15:52

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:10
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	31 Mar 2021 08:26:38
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:26:38
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	22 Mar 2021 19:52:16
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:52:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:15:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:10
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:52:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:15:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:10
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:52:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:15:52

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:10
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:26:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:26:38
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:26:38
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:52:16
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:52:16

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Form: Adverse Events (7)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:10
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:52:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:15:52

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:10
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:52:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:15:52

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:10
User entered '0'	System	31 Mar 2021 08:26:38

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:15:52

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:10
User entered 'I'	System	31 Mar 2021 08:26:38

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Folder: Adverse Events

Form: Adverse Events (7)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:10

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:15:52

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:31

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Folder: Adverse Events

Form: Adverse Events (8)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Per MM: This event is not considered a solicited adverse reaction. Please update, as appropriate. 2) Please confirm this event does not meet seriousness criteria.	(b) (4), (b) (6)	19 Apr 2021 14:45:48
' (Site from DM).		
Query 'Per MM: This event is not considered a solicited adverse reaction. Please update, as appropriate. 2) Please confirm this event does not meet seriousness criteria.	(b) (4), (b) (6)	16 Apr 2021 04:01:02
' answered with 'updated' (Site from DM).		
User opened query 'Per MM: This event is not considered a solicited adverse reaction. Please update, as appropriate. 2) Please confirm this event does not meet seriousness criteria.	(b) (4), (b) (6)	12 Apr 2021 12:54:26
' (Site from DM).		
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Hepatobiliary and spleen infections, PT: Cholecystitis infective, LLT: Gangrenous cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 07:34:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 07:34:28
Data point term sent to Coder	System	22 Mar 2021 19:53:05
User entered 'Acute Ganrenous Cholecystitis'	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:52:42

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:15:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:24:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:24:57
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:24:57
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:52:42
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:52:42

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:15:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 04:00:53
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:24:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:24:57
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:24:57
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:52:42
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:52:42

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:15:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:24:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:24:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:24:57
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:52:42
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:52:42

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:15:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:24:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:24:57
User entered '23 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:24:57
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:52:42
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:52:42

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:52:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:15:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:31
User entered empty.	System	22 Mar 2021 19:52:42

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:15:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:24:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:24:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:24:57
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:52:42
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:52:42

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:15:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '04 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:24:57
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:52:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:15:52

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:52:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:15:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:31
User entered empty.	System	22 Mar 2021 19:52:42

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:15:52

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:24:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:24:57
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:24:57
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:52:42
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:52:42

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:15:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:24:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:24:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:24:57
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:52:42
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:52:42

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:15:52

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:52:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:15:52

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:52:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:15:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:52:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:15:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:52:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:15:52

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:52:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:15:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:52:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:15:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:52:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:15:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:52:42
	(b) (4)	

US3252553

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:15:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:52:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:15:52

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:52:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:15:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:24:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:24:57
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:24:57
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:52:42
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:52:42

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:15:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:24:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:24:57
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:24:57
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:52:42
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:52:42

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:15:52

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:24:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:24:57
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:24:57
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:52:42
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:52:42

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:15:52

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	31 Mar 2021 08:24:57
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:24:57
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	22 Mar 2021 19:52:42
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:52:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:15:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:52:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:15:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:52:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:15:52

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:24:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:24:57
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:24:57
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:52:42
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:52:42

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:15:52

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:52:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:15:52

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:52:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:15:52

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:31
User entered '0'	System	31 Mar 2021 08:24:57

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:15:52

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:31
User entered '1'	System	31 Mar 2021 08:24:57

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:15:52

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:31

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:15:52

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:55

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:15:52

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:55
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Per MM: This event is not considered a solicited adverse reaction. Please update, as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 14:46:52
Query 'Per MM: This event is not considered a solicited adverse reaction. Please update, as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 03:59:35
User opened query 'Per MM: This event is not considered a solicited adverse reaction. Please update, as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 13:00:54
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Enterococcal infections, PT: Urinary tract infection enterococcal, LLT: Enterococcal urinary tract infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 10:28:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 10:28:32
Data point term sent to Coder	System	22 Mar 2021 19:54:20
User entered 'Enterococcus faecalis urinary tract infection'	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:53:09

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:15:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:55
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:21:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:21:01
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:21:01
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:53:09
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:53:09

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:15:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:55
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 03:59:26
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:21:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:21:01
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:21:01
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:53:09
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:53:09

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:15:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:55
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:21:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:21:01
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:21:01
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:53:09
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:53:09

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Folder: Adverse Events

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Generated On: 09 Jun 2021 16:15:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:55
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:21:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:21:01
User entered '23 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:21:01
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:53:09
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:53:09

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:15:52

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:55
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	31 Mar 2021 08:21:44
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:21:44
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	31 Mar 2021 08:21:01
User entered '00:00' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:21:01
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:53:09
	(b) (4)	

US3252553

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:15:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:55
User entered empty.	System	31 Mar 2021 08:21:44
User entered '23 Oct 2020 00:00'	System	31 Mar 2021 08:21:01
User entered empty.	System	22 Mar 2021 19:53:09

US3252553

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:15:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:55
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:21:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:21:01
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:21:01
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:53:09
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:53:09

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Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:15:52

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:55
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '04 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:21:01
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:53:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:15:52

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:55
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:53:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:15:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:55
User entered empty.	System	22 Mar 2021 19:53:09

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:15:52

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:55
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:21:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:21:01
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:21:01
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:53:09
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:53:09

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:15:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:55
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:21:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:21:01
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:21:01
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:53:09
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:53:09

US3252553

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:15:52

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:55
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:53:09
	(b) (4)	

US3252553

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:15:52

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:55
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:53:09
	(b) (4)	

US3252553

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:15:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:55
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:53:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:15:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:55
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:53:09
	(b) (4)	

US3252553

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:15:52

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:55
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:53:09
	(b) (4)	

US3252553

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:15:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:55
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:53:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:15:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:55
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:53:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:15:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:55
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:53:09
	(b) (4)	

US3252553

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:15:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:55
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:53:09
	(b) (4)	

US3252553

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:15:52

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:55
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:53:09
	(b) (4)	

US3252553

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:15:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:55
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:21:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:21:01
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:21:01
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:53:09
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:53:09

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:15:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:55
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:21:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:21:01
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:21:01
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:53:09
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:53:09

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:15:52

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:55
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:21:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:21:01
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:21:01
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:53:09
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:53:09

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:15:52

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:55
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	31 Mar 2021 08:21:01
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:21:01
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	22 Mar 2021 19:53:09
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:53:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:15:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:55
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:53:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:15:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:55
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:53:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:15:52

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:55
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:21:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:21:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:21:01
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:53:09
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:53:09

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:15:52

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:55
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:53:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:55
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:53:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:15:52

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:55
User entered '0'	System	31 Mar 2021 08:21:01

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:15:52

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:55
User entered 'I'	System	31 Mar 2021 08:21:01

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:15:52

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:42:55

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:15:52

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:36

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:15:52

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:36
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Procedural related injuries and complications NEC, HLT: Gastrointestinal and hepatobiliary procedural complications, PT: Post procedural bile leak, LLT: Post procedural bile leak - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 07:57:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 07:57:29
Data point term sent to Coder	System	22 Mar 2021 19:54:17
User entered 'Biliary Leak Status Post Stent Placement'	Xavier Morales (b) (4)	22 Mar 2021 19:53:30

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:15:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:36
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 07:58:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 07:58:22
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 07:58:22
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:53:30
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:53:30

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:15:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:36
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 07:58:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 07:58:37
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 07:58:37
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:53:30
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:53:30

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:15:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:36
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 07:58:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 07:58:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 07:58:52
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:53:30
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:53:30

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:15:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:36
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 07:59:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 07:59:08
User entered '23 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 07:59:08
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:53:30
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:53:30

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:15:52

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:36
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:53:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:15:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:36
User entered empty.	System	22 Mar 2021 19:53:30

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:15:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:36
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 07:59:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 07:59:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 07:59:25
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:53:30
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:53:30

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:15:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:36
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	31 Mar 2021 07:59:37
User entered '04 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 07:59:37
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	31 Mar 2021 07:59:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:53:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:15:52

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:36
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:53:30
	(b) (4)	

US3252553

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:15:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:36
User entered empty.	System	22 Mar 2021 19:53:30

US3252553

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:15:52

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:36
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 07:59:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 07:59:54
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 07:59:54
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:53:30
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:53:30

US3252553

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:15:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:36
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:00:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:00:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:00:05
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:53:30
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:53:30

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Folder: Adverse Events

Form: Adverse Events (10)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:36
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:53:30
	(b) (4)	

US3252553

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:15:52

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:36
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:53:30
	(b) (4)	

US3252553

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:15:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:36
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:53:30
	(b) (4)	

US3252553

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:15:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:36
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:53:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:15:52

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:36
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:53:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:15:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:36
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:53:30
	(b) (4)	

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:36
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:53:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:15:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:36
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:53:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:15:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:36
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:53:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:15:52

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:36
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:53:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:15:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:36
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:00:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:00:19
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:00:19
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:53:30
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:53:30

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:15:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:36
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:00:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:00:27
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:00:27
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:53:30
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:53:30

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:15:52

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:36
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Action Taken with Investigational System Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	31 Mar 2021 08:15:59
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	31 Mar 2021 08:15:59
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:02:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:02:07
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 08:02:07
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:02:07
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:01:32
User closed query 'Action Taken with Investigational System Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	31 Mar 2021 08:01:32
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	31 Mar 2021 08:01:32
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:01:32
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:00:45

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:15:52

Action taken with investigational product

Audit	User	Time (GMT)
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:00:45
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 08:00:45
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:00:45
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:53:30
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:53:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:15:52

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:36
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	31 Mar 2021 08:17:10
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:17:10
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	22 Mar 2021 19:53:30
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:53:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:15:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:36
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:53:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:15:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:36
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '0'	Xavier Morales (b) (4)	22 Mar 2021 19:53:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:15:52

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:36
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 08:01:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 08:01:44
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:01:44
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 19:53:30
User entered empty.	Xavier Morales (b) (4) (b) (4)	22 Mar 2021 19:53:30

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:15:52

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:36
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:53:30
	(b) (4)	

US3252553

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:15:52

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:36
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	Xavier Morales (b) (4)	22 Mar 2021 19:53:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:15:52

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:36
User entered '0'	System	31 Mar 2021 08:00:05

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:15:52

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:36
User entered '1'	System	31 Mar 2021 07:58:22

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:15:52

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:43:36

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:15:52

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:40:49
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:21:21
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	25 Sep 2020 08:10:31

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 08:12:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 08:12:42
Data point term sent to Coder	System	25 Sep 2020 08:12:07
User entered 'Losartan'	Nancy Torrence (b) (4) (b) (4)	25 Sep 2020 08:11:39

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'No (N)'	Nancy Torrence (b) (4)	25 Sep 2020 08:11:39
	(b) (4)	

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'Hypertension'	Nancy Torrence (b) (4)	25 Sep 2020 08:11:39
	(b) (4)	

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered '50'	Nancy Torrence (b) (4)	25 Sep 2020 08:11:39
	(b) (4)	

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'mg (mg)'	Nancy Torrence (b) (4)	25 Sep 2020 08:11:39
	(b) (4)	

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered empty.	Nancy Torrence (b) (4)	25 Sep 2020 08:11:39
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'once daily (QD)'	Nancy Torrence (b) (4)	25 Sep 2020 08:11:39
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered empty.	Nancy Torrence (b) (4)	25 Sep 2020 08:11:39
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'Oral (ORAL)'	Nancy Torrence (b) (4)	25 Sep 2020 08:11:39
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered empty.	Nancy Torrence (b) (4)	25 Sep 2020 08:11:39
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'UN UNK 2005'	Nancy Torrence (b) (4)	25 Sep 2020 08:11:39
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered '0'	Nancy Torrence (b) (4)	25 Sep 2020 08:11:39
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	25 Sep 2020 08:11:39
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered empty.	Nancy Torrence (b) (4)	25 Sep 2020 08:11:39
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'No (N)'	Nancy Torrence (b) (4)	25 Sep 2020 08:11:39
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 08:11:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 08:11:39

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 08:11:39

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:15:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 08:13:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 08:13:46
Data point term sent to Coder	System	25 Sep 2020 08:13:08
User entered 'Metoprolol'	Nancy Torrence (b) (4) (b) (4)	25 Sep 2020 08:12:48

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:15:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'No (N)'	Nancy Torrence (b) (4)	25 Sep 2020 08:12:48
	(b) (4)	

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:15:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'Hypertension'	Nancy Torrence (b) (4)	25 Sep 2020 08:12:48
	(b) (4)	

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:15:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered '50'	Nancy Torrence (b) (4)	25 Sep 2020 08:12:48
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:15:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'mg (mg)'	Nancy Torrence (b) (4)	25 Sep 2020 08:12:48
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:15:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered empty.	Nancy Torrence (b) (4)	25 Sep 2020 08:12:48
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:15:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'once daily (QD)'	Nancy Torrence (b) (4)	25 Sep 2020 08:12:48
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:15:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered empty.	Nancy Torrence (b) (4)	25 Sep 2020 08:12:48
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:15:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'Oral (ORAL)'	Nancy Torrence (b) (4)	25 Sep 2020 08:12:48
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:15:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered empty.	Nancy Torrence (b) (4)	25 Sep 2020 08:12:48
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'UN UNK 2019'	Nancy Torrence (b) (4)	25 Sep 2020 08:12:48
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:15:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered '0'	Nancy Torrence (b) (4)	25 Sep 2020 08:12:48
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:15:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	25 Sep 2020 08:12:48
	(b) (4)	

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:15:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered empty.	Nancy Torrence (b) (4)	25 Sep 2020 08:12:48
	(b) (4)	

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:15:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'No (N)'	Nancy Torrence (b) (4)	25 Sep 2020 08:12:48
	(b) (4)	

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:15:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 08:12:48

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:15:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 08:12:48

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:15:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 08:12:48

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:15:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 14:48:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 14:48:46
Data point term sent to Coder	System	17 Nov 2020 14:32:44
Coding entries removed.	Joanna Gurrola Mahoney (b) (4)	17 Nov 2020 14:32:00
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 08:15:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 08:15:49
Data point term sent to Coder	System	25 Sep 2020 08:15:08
User entered 'Aspirin'	Nancy Torrence (b) (4)	25 Sep 2020 08:14:12

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:15:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'Yes (Y)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	17 Nov 2020 14:32:00
User entered 'No (N)'	Nancy Torrence (b) (4)	25 Sep 2020 08:14:12
	(b) (4)	

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:15:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 10:13:38
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'Medication indication updated.' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	17 Nov 2020 14:32:30
User entered 'prophylaxis for cardiovascular disease' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	17 Nov 2020 14:32:00
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 09:35:34
User entered 'General Health'	Nancy Torrence (b) (4) (b) (4)	25 Sep 2020 08:14:12

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:15:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 10:13:52
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'Dosage updated.' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	17 Nov 2020 14:33:32
User entered '81' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	17 Nov 2020 14:32:00
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 09:35:41
User entered '51'	Nancy Torrence (b) (4) (b) (4)	25 Sep 2020 08:14:12

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:15:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'mg (mg)'	Nancy Torrence (b) (4)	25 Sep 2020 08:14:12
	(b) (4)	

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:15:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered empty.	Nancy Torrence (b) (4)	25 Sep 2020 08:14:12
	(b) (4)	

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:15:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'twice daily (BID)'	Nancy Torrence (b) (4)	25 Sep 2020 08:14:12
	(b) (4)	

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:15:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered empty.	Nancy Torrence (b) (4)	25 Sep 2020 08:14:12
	(b) (4)	

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:15:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'Oral (ORAL)'	Nancy Torrence (b) (4)	25 Sep 2020 08:14:12
	(b) (4)	

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:15:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered empty.	Nancy Torrence (b) (4)	25 Sep 2020 08:14:12
	(b) (4)	

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'UN UNK 2015'	Nancy Torrence (b) (4)	25 Sep 2020 08:14:12
	(b) (4)	

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:15:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered '0'	Nancy Torrence (b) (4)	25 Sep 2020 08:14:12
	(b) (4)	

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:15:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	25 Sep 2020 08:14:12
	(b) (4)	

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:15:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered empty.	Nancy Torrence (b) (4)	25 Sep 2020 08:14:12
	(b) (4)	

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:15:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'No (N)'	Nancy Torrence (b) (4)	25 Sep 2020 08:14:12
	(b) (4)	

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:15:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	25 Sep 2020 08:14:12

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:15:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 08:14:12

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:15:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 08:14:12

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:15:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 08:16:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 08:16:51
Data point term sent to Coder	System	25 Sep 2020 08:16:09
User entered 'Hydrochlorothiazide'	Nancy Torrence (b) (4) (b) (4)	25 Sep 2020 08:15:29

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:15:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'No (N)'	Nancy Torrence (b) (4)	25 Sep 2020 08:15:29
	(b) (4)	

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:15:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'Hypertension'	Nancy Torrence (b) (4)	25 Sep 2020 08:15:29
	(b) (4)	

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:15:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 10:14:20
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'has been updated to correct dosage' (Site from DM).	Xavier Morales (b) (4) (b) (4)	24 Nov 2020 18:09:10
User entered '12.5' reason for change: Data Entry Error	Xavier Morales (b) (4) (b) (4)	24 Nov 2020 18:09:02
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 09:35:49
User entered '2.5'	Nancy Torrence (b) (4) (b) (4)	25 Sep 2020 08:15:29

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:15:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'mg (mg)'	Nancy Torrence (b) (4)	25 Sep 2020 08:15:29
	(b) (4)	

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:15:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered empty.	Nancy Torrence (b) (4)	25 Sep 2020 08:15:29
	(b) (4)	

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:15:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'once daily (QD)'	Nancy Torrence (b) (4)	25 Sep 2020 08:15:29
	(b) (4)	

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:15:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered empty.	Nancy Torrence (b) (4)	25 Sep 2020 08:15:29
	(b) (4)	

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:15:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'Oral (ORAL)'	Nancy Torrence (b) (4)	25 Sep 2020 08:15:29
	(b) (4)	

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:15:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered empty.	Nancy Torrence (b) (4)	25 Sep 2020 08:15:29
	(b) (4)	

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'UN UNK 2019'	Nancy Torrence (b) (4)	25 Sep 2020 08:15:29
	(b) (4)	

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:15:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered '0'	Nancy Torrence (b) (4)	25 Sep 2020 08:15:29
	(b) (4)	

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:15:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	25 Sep 2020 08:15:29
	(b) (4)	

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:15:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered empty.	Nancy Torrence (b) (4)	25 Sep 2020 08:15:29
	(b) (4)	

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:15:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'No (N)'	Nancy Torrence (b) (4)	25 Sep 2020 08:15:29
	(b) (4)	

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:15:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 08:15:29

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:15:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 08:15:29

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:15:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 08:15:29

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:15:52

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:40
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALOXIN, PRODUCTSYNONYM: CEFALOXIN [CEFALOXIN] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Mar 2021 09:45:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Mar 2021 09:45:43
Data point term sent to Coder	System	11 Mar 2021 20:47:17
Coding entries removed.	Xavier Morales (b) (4)	11 Mar 2021 20:47:15
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:21:46
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALOXIN, PRODUCTSYNONYM: CEFALOXIN [CEFALOXIN] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Oct 2020 21:10:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Oct 2020 21:10:56
Data point term sent to Coder	System	15 Oct 2020 19:16:20
User entered 'cephalexin'	(b) (4), (b) (6)	15 Oct 2020 19:16:10

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:15:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:40
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:21:49
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 08:38:49
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' answered with 'this has been updated as in EMR it says no for this question.' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	24 Nov 2020 18:04:51
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	24 Nov 2020 18:04:13
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 12:00:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 19:16:10

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:15:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:40
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
DataPoint Un-verified.	Xavier Morales (b) (4)	11 Mar 2021 20:47:15
	(b) (4)	
User entered 'Nondisplaced fracture of the right scaphoid' reason for change: Data Entry Error	Xavier Morales (b) (4)	11 Mar 2021 20:47:15
User closed query 'Per CDM: Please verify if this pertains to (#2) RIGHT ANKLE FRACTURE (start date 23-OCT-2020) in the AE eCRF? If yes, note that the Con Med start date (13-OCT-2020) is prior to the start date of the AE? Please review and reconcile Con Med and AE dates as appropriate.' (Site from DM).	(b) (4)	
Query 'Per CDM: Please verify if this pertains to (#2) RIGHT ANKLE FRACTURE (start date 23-OCT-2020) in the AE eCRF? If yes, note that the Con Med start date (13-OCT-2020) is prior to the start date of the AE? Please review and reconcile Con Med and AE dates as appropriate.'	(b) (4), (b) (6)	25 Feb 2021 19:22:58
Query 'Per CDM: Please verify if this pertains to (#2) RIGHT ANKLE FRACTURE (start date 23-OCT-2020) in the AE eCRF? If yes, note that the Con Med start date (13-OCT-2020) is prior to the start date of the AE? Please review and reconcile Con Med and AE dates as appropriate.'	(b) (4), (b) (6)	25 Feb 2021 05:39:35
Query 'Per CDM: Please verify if this pertains to (#2) RIGHT ANKLE FRACTURE (start date 23-OCT-2020) in the AE eCRF? If yes, note that the Con Med start date (13-OCT-2020) is prior to the start date of the AE? Please review and reconcile Con Med and AE dates as appropriate.'	(b) (4), (b) (6)	
Query 'Per CDM: Please verify if this pertains to (#2) RIGHT ANKLE FRACTURE (start date 23-OCT-2020) in the AE eCRF? If yes, note that the Con Med start date (13-OCT-2020) is prior to the start date of the AE? Please review and reconcile Con Med and AE dates as appropriate.'	(b) (4), (b) (6)	19 Feb 2021 12:41:32
Query 'Per CDM: Please verify if this pertains to (#2) RIGHT ANKLE FRACTURE (start date 23-OCT-2020) in the AE eCRF? If yes, note that the Con Med start date (13-OCT-2020) is prior to the start date of the AE? Please review and reconcile Con Med and AE dates as appropriate.'	(b) (4), (b) (6)	27 Jan 2021 19:21:55
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:16:10
User entered 'Right Ankle fracture'	(b) (4), (b) (6)	

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:15:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:40
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:22:01
User entered '500'	(b) (4), (b) (6)	15 Oct 2020 19:16:10

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:15:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:40
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:22:04
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Oct 2020 19:16:10

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:15:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:40
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:22:05
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 19:16:10

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:15:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:40
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:22:07
User entered 'four times daily (QID)'	(b) (4), (b) (6)	15 Oct 2020 19:16:10

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:15:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:40
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:22:09
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 19:16:10

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:15:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:40
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:22:11
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	15 Oct 2020 19:16:10

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:15:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:40
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:22:12
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 19:16:10

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:15:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:40
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 10:45:59
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. answered with 'DATE OF AE HAS BEEN UPDATED ONCE MEDICAL RECORDS WERE OBTAINED' (Site from DM).	Xavier Morales (b) (4)	11 Mar 2021 20:47:31
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 14:58:04
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:22:15
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	15 Oct 2020 19:16:17
User entered '13 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 19:16:17
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	15 Oct 2020 19:16:10
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 19:16:10

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:15:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:40
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:22:17
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 19:16:10

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:15:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:40
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User closed query 'Per source, stop date is recorded as 23-Oct-2020. Please verify with source and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	23 Feb 2021 01:05:44
Query 'Per source, stop date is recorded as 23-Oct-2020. Please verify with source and update EDC accordingly.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 07:45:53
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 07:44:54
User opened query 'Per source, stop date is recorded as 23-Oct-2020. Please verify with source and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 19:07:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 19:16:10

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:15:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:40
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered '23 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 07:44:54
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 19:16:10

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:15:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:40
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:24:26
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 19:16:10

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:15:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:40
User entered '4'	System	15 Oct 2020 19:16:10

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:15:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:40
User entered '1'	System	15 Oct 2020 19:16:10

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:15:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:40
User entered '804 (804)'	System	15 Oct 2020 19:16:10

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:15:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:41
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Mar 2021 21:04:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	11 Mar 2021 20:49:19
Coding entries removed.	Xavier Morales (b) (4)	11 Mar 2021 20:49:05
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:24:34
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 19:18:32
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 19:18:32
	(b) (4)	
Data point term sent to Coder	System	15 Oct 2020 19:17:21
User entered 'Acetaminophen'	(b) (4), (b) (6)	15 Oct 2020 19:17:01
	(b) (4)	

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:15:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:41
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:24:37
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 19:17:01

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:15:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:41
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
DataPoint Un-verified.	Xavier Morales (b) (4)	11 Mar 2021 20:49:05
	(b) (4)	
User entered 'Nondisplaced fracture of the right scaphoid' reason for change: Data Entry Error	Xavier Morales (b) (4)	11 Mar 2021 20:49:05
User closed query 'Per CDM: Please verify if this pertains to (#2) RIGHT ANKLE FRACTURE (start date 23-OCT-2020) in the AE eCRF? If yes, note that the Con Med start date (13-OCT-2020) is prior to the start date of the AE? Please review and reconcile Con Med and AE dates as appropriate.' (Site from DM).	(b) (4)	
Query 'Per CDM: Please verify if this pertains to (#2) RIGHT ANKLE FRACTURE (start date 23-OCT-2020) in the AE eCRF? If yes, note that the Con Med start date (13-OCT-2020) is prior to the start date of the AE? Please review and reconcile Con Med and AE dates as appropriate.' answered with 'both are separate entries according to the source' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 19:23:04
User opened query 'Per CDM: Please verify if this pertains to (#2) RIGHT ANKLE FRACTURE (start date 23-OCT-2020) in the AE eCRF? If yes, note that the Con Med start date (13-OCT-2020) is prior to the start date of the AE? Please review and reconcile Con Med and AE dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 05:42:27
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 12:42:02
User entered 'Right Ankle fracture'	(b) (4), (b) (6)	27 Jan 2021 19:24:38
	(b) (4), (b) (6)	15 Oct 2020 19:17:01

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:15:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:41
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:24:40
User entered '500'	(b) (4), (b) (6)	15 Oct 2020 19:17:01

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:15:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:41
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:24:42
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Oct 2020 19:17:01

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:15:52

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:41
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:24:44
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 19:17:01

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:15:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:41
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User closed query 'Per source, frequency of medication is as needed. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	23 Feb 2021 01:05:02
Query 'Per source, frequency of medication is as needed. Please verify and update EDC accordingly.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 07:46:14
User entered 'as needed (PRN)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 07:46:07
User opened query 'Per source, frequency of medication is as needed. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 19:26:12
User entered 'once daily (QD)'	(b) (4), (b) (6)	15 Oct 2020 19:17:01

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:15:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:41
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 19:17:01

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:15:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:41
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:26:16
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	15 Oct 2020 19:17:01

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:15:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:41
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:26:19
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 19:17:01

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:15:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:41
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 10:46:12
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' answered with 'START DATE OF AE HAS BEEN UPDATED SINCE MEDICAL RECORDS WERE OBTAINED ' (Site from DM).	Xavier Morales (b) (4)	11 Mar 2021 20:48:50
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 14:57:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:26:20
User entered '13 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 19:17:01

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:15:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:41
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:26:22
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 19:17:01

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:15:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:41
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.	(b) (4), (b) (6)	29 Mar 2021 13:21:23
' (Site from DM).		
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.	(b) (4), (b) (6)	25 Mar 2021 03:09:54
' answered with 'UPDATED' (Site from DM).		
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 03:09:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 03:09:48
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.	(b) (4), (b) (6)	21 Mar 2021 16:10:26
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:26:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 19:17:01

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:15:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:41
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 03:09:48
User entered '05 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 03:09:48
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:26:25
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 19:17:01

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:15:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:41
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:26:27
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 19:17:01

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:15:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:41
User entered empty.	System	18 Feb 2021 07:46:07
User entered '1'	System	15 Oct 2020 19:17:01

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:15:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:41
User entered empty.	System	18 Feb 2021 07:46:07
User entered '1'	System	15 Oct 2020 19:17:01

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:15:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:41
User entered empty.	System	18 Feb 2021 07:46:07
User entered '804 (804)'	System	15 Oct 2020 19:17:01

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:15:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:48
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: ZOSYN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 04:15:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	07 Apr 2021 04:14:48
User entered 'Zosyn'	(b) (4), (b) (6)	07 Apr 2021 04:14:13

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:15:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:48
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered 'No (N)'	(b) (4), (b) (6)	07 Apr 2021 04:14:13

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:15:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:48
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered 'Acute cholecystitis and Sepsis'	(b) (4), (b) (6)	07 Apr 2021 04:14:13

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:15:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:48
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered '3.3'	(b) (4), (b) (6)	07 Apr 2021 04:14:13

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:15:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:48
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered 'g (g)'	(b) (4), (b) (6)	07 Apr 2021 04:14:13

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:15:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:48
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered empty.	(b) (4), (b) (6)	07 Apr 2021 04:14:13

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:15:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:48
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered 'three times daily (TID)'	(b) (4), (b) (6)	07 Apr 2021 04:14:13

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:15:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:48
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered empty.	(b) (4), (b) (6)	07 Apr 2021 04:14:13

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:15:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:48
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	07 Apr 2021 04:14:13

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:15:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:48
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered empty.	(b) (4), (b) (6)	07 Apr 2021 04:14:13

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:48
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered '23 Oct 2020'	(b) (4), (b) (6)	07 Apr 2021 04:14:13

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:15:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:48
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered '0'	(b) (4), (b) (6)	07 Apr 2021 04:14:13

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:15:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:48
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Apr 2021 04:14:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Apr 2021 04:14:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 04:14:21
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Apr 2021 04:14:13
User entered empty.	(b) (4), (b) (6)	07 Apr 2021 04:14:13

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:15:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:48
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered '04 Nov 2020'	(b) (4), (b) (6)	07 Apr 2021 04:14:13

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:15:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:48
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered 'No (N)'	(b) (4), (b) (6)	07 Apr 2021 04:14:13

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:15:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:48
User entered '3'	System	07 Apr 2021 04:14:13

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:15:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:48
User entered '1'	System	07 Apr 2021 04:14:13

US3252553

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:15:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:48
User entered '804 (804)'	System	07 Apr 2021 04:14:13

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:15:52

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:40:49
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
DataPoint Un-verified.	Xavier Morales (b) (4)	11 Mar 2021 20:37:35
Signature has been broken.	(b) (4) Xavier Morales (b) (4)	11 Mar 2021 20:37:35
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Xavier Morales (b) (4)	11 Mar 2021 20:37:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
User closed query 'Per source, subject was discontinued from study as of 01-Dec-2020. Please update the End of Study Dosing Discontinuation page due to not receiving dose 2 at Day 29. Please also complete the End of Study / Study Discontinuation page due to subject withdrawal. For any pending queries that cannot be answered, please indicate subject withdrawal/LTFU.' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 01:46:55
Query 'Per source, subject was discontinued from study as of 01-Dec-2020. Please update the End of Study Dosing Discontinuation page due to not receiving dose 2 at Day 29. Please also complete the End of Study / Study Discontinuation page due to subject withdrawal. For any pending queries that cannot be answered, please indicate subject withdrawal/LTFU.' answered with 'End of Study Dosing Discontinuation page is filled' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 06:37:21
User opened query 'Per source, subject was discontinued from study as of 01-Dec-2020. Please update the End of Study Dosing Discontinuation page due to not receiving dose 2 at Day 29. Please also complete the End of Study / Study Discontinuation page due to subject withdrawal. For any pending queries that cannot be answered, please indicate subject withdrawal/LTFU.' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 18:49:54
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:26:48
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	25 Sep 2020 08:16:01

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:15:52

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered '14 Oct 2020'	Xavier Morales (b) (4)	11 Mar 2021 20:38:05
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:15:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'X-RAYS OF RIGHT WRIST, RIGHT KNEE, AND RIGHT ANKLE'	Xavier Morales (b) (4)	11 Mar 2021 20:38:05

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:15:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Xavier Morales (b) (4)	11 Mar 2021 20:38:11
User entered 'Diagnostic (DIAGNOSTIC)'	Xavier Morales (b) (4)	11 Mar 2021 20:38:05

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:15:52

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered empty.	Xavier Morales (b) (4)	11 Mar 2021 20:38:05
	(b) (4)	

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:15:52

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered '19 Oct 2020'	Xavier Morales (b) (4)	11 Mar 2021 20:39:10
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:15:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'X-RAYS OF RIGHT WRIST, RIGHT KNEE, AND RIGHT ANKLE'	Xavier Morales (b) (4)	11 Mar 2021 20:39:10

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:15:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'Adverse Event (AE)'	Xavier Morales (b) (4)	11 Mar 2021 20:39:10
	(b) (4)	

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:15:52

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered empty.	Xavier Morales (b) (4)	11 Mar 2021 20:39:10
	(b) (4)	

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:15:52

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered '13 Nov 2020'	Xavier Morales (b) (4)	11 Mar 2021 20:39:35
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:15:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'X-RAYS OF RIGHT WRIST AND RIGHT ANKLE'	Xavier Morales (b) (4) (b) (4)	11 Mar 2021 20:39:35

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:15:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'Adverse Event (AE)'	Xavier Morales (b) (4)	11 Mar 2021 20:39:35
	(b) (4)	

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:15:52

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered empty.	Xavier Morales (b) (4)	11 Mar 2021 20:39:35
	(b) (4)	

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:15:52

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered '25 Nov 2020'	Xavier Morales (b) (4)	11 Mar 2021 20:39:55
	(b) (4)	

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:15:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'X-RAYS OF RIGHT ANKLE'	Xavier Morales (b) (4)	11 Mar 2021 20:39:55
	(b) (4)	

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:15:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'Adverse Event (AE)'	Xavier Morales (b) (4)	11 Mar 2021 20:39:55
	(b) (4)	

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:15:52

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered empty.	Xavier Morales (b) (4)	11 Mar 2021 20:39:55
	(b) (4)	

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:15:52

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered '16 Dec 2020'	Xavier Morales (b) (4)	11 Mar 2021 20:40:15
	(b) (4)	

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:15:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'X-RAYS OF RIGHT WRIST AND RIGHT ANKLE'	Xavier Morales (b) (4) (b) (4)	11 Mar 2021 20:40:15

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:15:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'Adverse Event (AE)'	Xavier Morales (b) (4)	11 Mar 2021 20:40:15
	(b) (4)	

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:15:52

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered empty.	Xavier Morales (b) (4)	11 Mar 2021 20:40:15
	(b) (4)	

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:15:52

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered '13 Jan 2021'	Xavier Morales (b) (4)	11 Mar 2021 20:40:47
	(b) (4)	

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:15:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'X-RAYS OF RIGHT WRIST AND RIGHT ANKLE'	Xavier Morales (b) (4) (b) (4)	11 Mar 2021 20:40:47

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:15:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered 'Adverse Event (AE)'	Xavier Morales (b) (4)	11 Mar 2021 20:40:47
	(b) (4)	

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:15:52

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User entered empty.	Xavier Morales (b) (4)	11 Mar 2021 20:40:47
	(b) (4)	

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:15:52

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:29:51
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '23 Oct 2020'	(b) (4), (b) (6)	13 Apr 2021 07:08:06

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:15:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:29:51
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered 'Laparoscopic converted to open subtotal cholecystectomy'	(b) (4), (b) (6)	13 Apr 2021 07:08:06

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:15:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:29:51
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	13 Apr 2021 07:08:06

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:15:52

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:29:51
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 07:08:06

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 16:15:52

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:10
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '25 Oct 2020'	(b) (4), (b) (6)	13 Apr 2021 07:08:24

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 16:15:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:10
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered 'Exploratory Laparotomy'	(b) (4), (b) (6)	13 Apr 2021 07:08:24

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 16:15:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:10
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	13 Apr 2021 07:08:24

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 16:15:52

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:10
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 07:08:24

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 16:15:52

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:14
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '29 Oct 2020'	(b) (4), (b) (6)	13 Apr 2021 07:08:39

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 16:15:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:14
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered 'MIDLINE PLACEMENT'	(b) (4), (b) (6)	13 Apr 2021 07:08:39

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 16:15:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:14
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	13 Apr 2021 07:08:39

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 16:15:52

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:14
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 07:08:39

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 16:15:52

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:24
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '25 Oct 2020'	(b) (4), (b) (6)	13 Apr 2021 07:08:53

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 16:15:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:24
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered 'PARTIAL CHOLECYSTECTOMY (POSTERIOR WALL)'	(b) (4), (b) (6)	13 Apr 2021 07:08:53

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 16:15:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:24
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	13 Apr 2021 07:08:53

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 16:15:52

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:24
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 07:08:53

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 16:15:52

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:29
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '25 Oct 2020'	(b) (4), (b) (6)	13 Apr 2021 07:09:08

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 16:15:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:29
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered 'CONTROL OF CYSTIC DUCT WITH CLIPS'	(b) (4), (b) (6)	13 Apr 2021 07:09:08

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 16:15:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:29
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	13 Apr 2021 07:09:08

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 16:15:52

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:29
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 07:09:08

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 16:15:52

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '25 Oct 2020'	(b) (4), (b) (6)	13 Apr 2021 07:09:23

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 16:15:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered 'ABDOMINAL LAVAGE'	(b) (4), (b) (6)	13 Apr 2021 07:09:23

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 16:15:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	13 Apr 2021 07:09:23

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 16:15:52

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 07:09:23

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 16:15:52

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '25 Oct 2020'	(b) (4), (b) (6)	13 Apr 2021 07:09:35

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 16:15:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered 'FASCIAL CLOSURE'	(b) (4), (b) (6)	13 Apr 2021 07:09:35

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 16:15:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	13 Apr 2021 07:09:35

US3252553

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 16:15:52

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 07:09:35

US3252553

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:15:52

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:15
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 05:36:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Feb 2021 05:36:03
User entered '01 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 05:36:03
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Feb 2021 07:58:41
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 07:58:41
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Feb 2021 07:58:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Feb 2021 07:58:04
User entered '1 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 07:58:04
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Feb 2021 07:57:57
User entered empty.	(b) (4), (b) (6)	15 Feb 2021 07:57:57

US3252553

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:15:52

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:15
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 08:15:59
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:15:59
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 05:36:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Feb 2021 05:36:03
User entered 'Lost To Follow-up (LOST TO FOLLOW-UP)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 05:36:03
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Feb 2021 07:58:41
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 07:58:41
User entered 'Other (OTHER)'	(b) (4), (b) (6)	15 Feb 2021 07:57:57

US3252553

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:15:52

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)	27 Apr 2021 10:45:15
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 08:15:59
User entered 'patient discontinued due to AE# 9,8,7,6,5,4' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 08:15:59
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	15 Feb 2021 07:58:41
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	15 Feb 2021 07:57:57
User entered empty.	(b) (4), (b) (6)	15 Feb 2021 07:57:57

US3252553

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:15:52

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:15
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	08 Mar 2021 12:16:30
Query 'Data is required. Please complete.' answered with 'data entry error' (Site from System).	(b) (4), (b) (6)	08 Mar 2021 07:27:15
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Mar 2021 07:27:03
Signature has been broken.	(b) (4), (b) (6)	08 Mar 2021 07:27:03
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 07:27:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
User entered '01 Dec 2020'	(b) (4), (b) (6)	18 Feb 2021 06:25:50

US3252553

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:15:52

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:15
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:43:23
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	08 Mar 2021 12:16:32
Query 'Data is required. Please complete.' answered with 'data entry error' (Site from System).	(b) (4), (b) (6)	08 Mar 2021 07:27:27
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Mar 2021 07:27:03
Signature has been broken.	(b) (4), (b) (6)	08 Mar 2021 07:27:03
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 07:27:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
User entered 'Lost To Follow-up (LOST TO FOLLOW-UP)'	(b) (4), (b) (6)	18 Feb 2021 06:25:50

US3252553

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:15:52

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)	27 Apr 2021 10:45:15
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 06:25:50

US3252553

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:15:52

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:15
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 06:25:50

US3252553

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:15:52

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:15
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 06:25:50

US3252553

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:15:52

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:15
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 06:25:50

US3252553

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:15:52

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:15
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 06:25:50

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'USA-US108-2020-MRNA-1273-P301000011'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'Yes (Y)'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	System	11 Mar 2021 14:13:06
Signature has been broken.	System	11 Mar 2021 14:13:06
User entered 'No (N)'	System	11 Mar 2021 14:13:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Yes (Y)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 18:26:17
Un-reviewed for Safety.	System	24 Mar 2021 18:25:23
Signature has been broken.	System	24 Mar 2021 18:25:23
User entered 'Yes (Y)'	System	24 Mar 2021 18:25:23
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'Yes (Y)'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	System	11 Mar 2021 14:13:06
Signature has been broken.	System	11 Mar 2021 14:13:06
User entered 'No (N)'	System	11 Mar 2021 14:13:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Yes (Y)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Joel'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Solis'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered '5201 N. 10th Street'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
Signature has been broken.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User entered '1020 Zinnia Ave' reason for change:	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
Data Entry Error	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered '5201 N. 10th Street'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Mcallen'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'TX'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'carmpa'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
Signature has been broken.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 20:03:38
Un-reviewed for Safety.	System	25 Nov 2020 12:45:11
User entered 'carmpa'	System	25 Nov 2020 12:45:11
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 12:45:01
Un-reviewed for Safety.	Joanna Gurrola Mahoney	12 Nov 2020 23:27:50
	(b) (4)	
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney	12 Nov 2020 23:27:50
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'carmpa'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 12:45:01
User entered 'US'	System	28 Oct 2020 21:01:02

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	22 Apr 2021 17:55:11
User entered '12'	System	15 Apr 2021 14:11:36
User entered '11'	System	07 Apr 2021 13:34:43
User entered '10'	System	31 Mar 2021 17:35:34
User entered '9'	System	24 Mar 2021 18:36:02
User entered '8'	System	24 Mar 2021 18:26:47
User entered '7'	System	19 Mar 2021 14:23:09
User entered '6'	System	15 Mar 2021 15:37:29
User entered '5'	System	12 Mar 2021 16:25:57
User entered '4'	System	26 Feb 2021 16:41:22
User entered '3'	System	18 Feb 2021 20:03:35
User entered '2'	System	25 Nov 2020 12:45:11
User entered '1'	System	28 Oct 2020 21:01:02

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'USA-US108-2020-MRNA-1273-P301000011'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'Yes (Y)'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	System	11 Mar 2021 14:13:06
Signature has been broken.	System	11 Mar 2021 14:13:06
User entered 'No (N)'	System	11 Mar 2021 14:13:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Yes (Y)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 18:26:17
Un-reviewed for Safety.	System	24 Mar 2021 18:25:23
Signature has been broken.	System	24 Mar 2021 18:25:23
User entered 'Yes (Y)'	System	24 Mar 2021 18:25:23
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'Yes (Y)'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	System	11 Mar 2021 14:13:06
Signature has been broken.	System	11 Mar 2021 14:13:06
User entered 'No (N)'	System	11 Mar 2021 14:13:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Yes (Y)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Joel'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Solis'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered '5201 N. 10th Street'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
Signature has been broken.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User entered '1020 Zinnia Ave' reason for change:	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
Data Entry Error	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered '5201 N. 10th Street'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Mcallen'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'TX'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'carmpa'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
Signature has been broken.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 20:03:38
Un-reviewed for Safety.	System	25 Nov 2020 12:45:11
User entered 'carmpa'	System	25 Nov 2020 12:45:11
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 12:45:01
Un-reviewed for Safety.	Joanna Gurrola Mahoney	12 Nov 2020 23:27:50
	(b) (4)	
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney	12 Nov 2020 23:27:50
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'carmpa'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 12:45:01
User entered 'US'	System	28 Oct 2020 21:01:02

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	22 Apr 2021 17:55:11
User entered '12'	System	15 Apr 2021 14:11:36
User entered '11'	System	07 Apr 2021 13:34:43
User entered '10'	System	31 Mar 2021 17:35:34
User entered '9'	System	24 Mar 2021 18:36:02
User entered '8'	System	24 Mar 2021 18:26:47
User entered '7'	System	19 Mar 2021 14:23:09
User entered '6'	System	15 Mar 2021 15:37:29
User entered '5'	System	12 Mar 2021 16:25:57
User entered '4'	System	26 Feb 2021 16:41:22
User entered '3'	System	18 Feb 2021 20:03:35
User entered '2'	System	25 Nov 2020 12:45:11
User entered '1'	System	28 Oct 2020 21:01:02

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:15:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
User entered '28/Oct/2020 17:01'	System	28 Oct 2020 21:01:02

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:15:52

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.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 12:45:01
User entered 'I'	(b) (4), (b) (6)	28 Oct 2020 21:01:02

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'USA-US108-2020-MRNA-1273-P301000011'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'Yes (Y)'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	System	11 Mar 2021 14:13:06
Signature has been broken.	System	11 Mar 2021 14:13:06
User entered 'No (N)'	System	11 Mar 2021 14:13:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Yes (Y)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 18:26:17
Un-reviewed for Safety.	System	24 Mar 2021 18:25:23
Signature has been broken.	System	24 Mar 2021 18:25:23
User entered 'Yes (Y)'	System	24 Mar 2021 18:25:23
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'Yes (Y)'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	System	11 Mar 2021 14:13:06
Signature has been broken.	System	11 Mar 2021 14:13:06
User entered 'No (N)'	System	11 Mar 2021 14:13:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Yes (Y)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Joel'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Solis'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered '5201 N. 10th Street'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
Signature has been broken.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User entered '1020 Zinnia Ave' reason for change:	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
Data Entry Error	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered '5201 N. 10th Street'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Mcallen'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'TX'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'carmpa'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
Signature has been broken.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 20:03:38
Un-reviewed for Safety.	System	25 Nov 2020 12:45:11
User entered 'carmpa'	System	25 Nov 2020 12:45:11
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 12:45:01
Un-reviewed for Safety.	Joanna Gurrola Mahoney	12 Nov 2020 23:27:50
	(b) (4)	
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney	12 Nov 2020 23:27:50
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'carmpa'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 12:45:01
User entered 'US'	System	28 Oct 2020 21:01:02

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	22 Apr 2021 17:55:11
User entered '12'	System	15 Apr 2021 14:11:36
User entered '11'	System	07 Apr 2021 13:34:43
User entered '10'	System	31 Mar 2021 17:35:34
User entered '9'	System	24 Mar 2021 18:36:02
User entered '8'	System	24 Mar 2021 18:26:47
User entered '7'	System	19 Mar 2021 14:23:09
User entered '6'	System	15 Mar 2021 15:37:29
User entered '5'	System	12 Mar 2021 16:25:57
User entered '4'	System	26 Feb 2021 16:41:22
User entered '3'	System	18 Feb 2021 20:03:35
User entered '2'	System	25 Nov 2020 12:45:11
User entered '1'	System	28 Oct 2020 21:01:02

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:15:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
User entered '25/Nov/2020 12:45'	System	25 Nov 2020 12:45:11

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:15:52

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.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 20:03:38
User entered 'I'	(b) (4), (b) (6)	25 Nov 2020 12:45:11

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'USA-US108-2020-MRNA-1273-P301000011'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'Yes (Y)'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	System	11 Mar 2021 14:13:06
Signature has been broken.	System	11 Mar 2021 14:13:06
User entered 'No (N)'	System	11 Mar 2021 14:13:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Yes (Y)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 18:26:17
Un-reviewed for Safety.	System	24 Mar 2021 18:25:23
Signature has been broken.	System	24 Mar 2021 18:25:23
User entered 'Yes (Y)'	System	24 Mar 2021 18:25:23
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'Yes (Y)'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	System	11 Mar 2021 14:13:06
Signature has been broken.	System	11 Mar 2021 14:13:06
User entered 'No (N)'	System	11 Mar 2021 14:13:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Yes (Y)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Joel'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Solis'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered '5201 N. 10th Street'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
Signature has been broken.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User entered '1020 Zinnia Ave' reason for change:	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
Data Entry Error	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered '5201 N. 10th Street'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Mcallen'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'TX'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'carmpa'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
Signature has been broken.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 20:03:38
Un-reviewed for Safety.	System	25 Nov 2020 12:45:11
User entered 'carmpa'	System	25 Nov 2020 12:45:11
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 12:45:01
Un-reviewed for Safety.	Joanna Gurrola Mahoney	12 Nov 2020 23:27:50
	(b) (4)	
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney	12 Nov 2020 23:27:50
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'carmpa'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 12:45:01
User entered 'US'	System	28 Oct 2020 21:01:02

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	22 Apr 2021 17:55:11
User entered '12'	System	15 Apr 2021 14:11:36
User entered '11'	System	07 Apr 2021 13:34:43
User entered '10'	System	31 Mar 2021 17:35:34
User entered '9'	System	24 Mar 2021 18:36:02
User entered '8'	System	24 Mar 2021 18:26:47
User entered '7'	System	19 Mar 2021 14:23:09
User entered '6'	System	15 Mar 2021 15:37:29
User entered '5'	System	12 Mar 2021 16:25:57
User entered '4'	System	26 Feb 2021 16:41:22
User entered '3'	System	18 Feb 2021 20:03:35
User entered '2'	System	25 Nov 2020 12:45:11
User entered '1'	System	28 Oct 2020 21:01:02

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:15:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
User entered '18/Feb/2021 15:03'	System	18 Feb 2021 20:03:35

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:15:52

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.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 20:03:38
User entered 'I'	(b) (4), (b) (6)	18 Feb 2021 20:03:35

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'USA-US108-2020-MRNA-1273-P301000011'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'Yes (Y)'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	System	11 Mar 2021 14:13:06
Signature has been broken.	System	11 Mar 2021 14:13:06
User entered 'No (N)'	System	11 Mar 2021 14:13:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Yes (Y)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 18:26:17
Un-reviewed for Safety.	System	24 Mar 2021 18:25:23
Signature has been broken.	System	24 Mar 2021 18:25:23
User entered 'Yes (Y)'	System	24 Mar 2021 18:25:23
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'Yes (Y)'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	System	11 Mar 2021 14:13:06
Signature has been broken.	System	11 Mar 2021 14:13:06
User entered 'No (N)'	System	11 Mar 2021 14:13:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Yes (Y)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Joel'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Solis'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered '5201 N. 10th Street'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
Signature has been broken.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User entered '1020 Zinnia Ave' reason for change:	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
Data Entry Error	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered '5201 N. 10th Street'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Mcallen'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'TX'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'carmpa'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
Signature has been broken.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 20:03:38
Un-reviewed for Safety.	System	25 Nov 2020 12:45:11
User entered 'carmpa'	System	25 Nov 2020 12:45:11
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 12:45:01
Un-reviewed for Safety.	Joanna Gurrola Mahoney	12 Nov 2020 23:27:50
	(b) (4)	
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney	12 Nov 2020 23:27:50
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'carmpa'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 12:45:01
User entered 'US'	System	28 Oct 2020 21:01:02

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	22 Apr 2021 17:55:11
User entered '12'	System	15 Apr 2021 14:11:36
User entered '11'	System	07 Apr 2021 13:34:43
User entered '10'	System	31 Mar 2021 17:35:34
User entered '9'	System	24 Mar 2021 18:36:02
User entered '8'	System	24 Mar 2021 18:26:47
User entered '7'	System	19 Mar 2021 14:23:09
User entered '6'	System	15 Mar 2021 15:37:29
User entered '5'	System	12 Mar 2021 16:25:57
User entered '4'	System	26 Feb 2021 16:41:22
User entered '3'	System	18 Feb 2021 20:03:35
User entered '2'	System	25 Nov 2020 12:45:11
User entered '1'	System	28 Oct 2020 21:01:02

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:15:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
User entered '26/Feb/2021 10:41'	System	26 Feb 2021 16:41:22

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:15:52

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)
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
User entered 'I'	(b) (4), (b) (6)	26 Feb 2021 16:41:22

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'USA-US108-2020-MRNA-1273-P301000011'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'Yes (Y)'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	System	11 Mar 2021 14:13:06
Signature has been broken.	System	11 Mar 2021 14:13:06
User entered 'No (N)'	System	11 Mar 2021 14:13:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Yes (Y)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 18:26:17
Un-reviewed for Safety.	System	24 Mar 2021 18:25:23
Signature has been broken.	System	24 Mar 2021 18:25:23
User entered 'Yes (Y)'	System	24 Mar 2021 18:25:23
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'Yes (Y)'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	System	11 Mar 2021 14:13:06
Signature has been broken.	System	11 Mar 2021 14:13:06
User entered 'No (N)'	System	11 Mar 2021 14:13:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Yes (Y)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Joel'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Solis'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered '5201 N. 10th Street'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
Signature has been broken.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User entered '1020 Zinnia Ave' reason for change:	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
Data Entry Error	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered '5201 N. 10th Street'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Mcallen'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'TX'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'carmpa'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
Signature has been broken.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 20:03:38
Un-reviewed for Safety.	System	25 Nov 2020 12:45:11
User entered 'carmpa'	System	25 Nov 2020 12:45:11
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 12:45:01
Un-reviewed for Safety.	Joanna Gurrola Mahoney	12 Nov 2020 23:27:50
	(b) (4)	
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney	12 Nov 2020 23:27:50
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'carmpa'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 12:45:01
User entered 'US'	System	28 Oct 2020 21:01:02

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	22 Apr 2021 17:55:11
User entered '12'	System	15 Apr 2021 14:11:36
User entered '11'	System	07 Apr 2021 13:34:43
User entered '10'	System	31 Mar 2021 17:35:34
User entered '9'	System	24 Mar 2021 18:36:02
User entered '8'	System	24 Mar 2021 18:26:47
User entered '7'	System	19 Mar 2021 14:23:09
User entered '6'	System	15 Mar 2021 15:37:29
User entered '5'	System	12 Mar 2021 16:25:57
User entered '4'	System	26 Feb 2021 16:41:22
User entered '3'	System	18 Feb 2021 20:03:35
User entered '2'	System	25 Nov 2020 12:45:11
User entered '1'	System	28 Oct 2020 21:01:02

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:15:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered '12/Mar/2021 11:25'	System	12 Mar 2021 16:25:57

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:15:52

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.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'I'	(b) (4), (b) (6)	12 Mar 2021 16:25:57

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'USA-US108-2020-MRNA-1273-P301000011'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'Yes (Y)'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	System	11 Mar 2021 14:13:06
Signature has been broken.	System	11 Mar 2021 14:13:06
User entered 'No (N)'	System	11 Mar 2021 14:13:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Yes (Y)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 18:26:17
Un-reviewed for Safety.	System	24 Mar 2021 18:25:23
Signature has been broken.	System	24 Mar 2021 18:25:23
User entered 'Yes (Y)'	System	24 Mar 2021 18:25:23
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'Yes (Y)'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	System	11 Mar 2021 14:13:06
Signature has been broken.	System	11 Mar 2021 14:13:06
User entered 'No (N)'	System	11 Mar 2021 14:13:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Yes (Y)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Joel'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Solis'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered '5201 N. 10th Street'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
Signature has been broken.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User entered '1020 Zinnia Ave' reason for change:	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
Data Entry Error	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered '5201 N. 10th Street'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Mcallen'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'TX'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'carmpa'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
Signature has been broken.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 20:03:38
Un-reviewed for Safety.	System	25 Nov 2020 12:45:11
User entered 'carmpa'	System	25 Nov 2020 12:45:11
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 12:45:01
Un-reviewed for Safety.	Joanna Gurrola Mahoney	12 Nov 2020 23:27:50
	(b) (4)	
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney	12 Nov 2020 23:27:50
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'carmpa'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 12:45:01
User entered 'US'	System	28 Oct 2020 21:01:02

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	22 Apr 2021 17:55:11
User entered '12'	System	15 Apr 2021 14:11:36
User entered '11'	System	07 Apr 2021 13:34:43
User entered '10'	System	31 Mar 2021 17:35:34
User entered '9'	System	24 Mar 2021 18:36:02
User entered '8'	System	24 Mar 2021 18:26:47
User entered '7'	System	19 Mar 2021 14:23:09
User entered '6'	System	15 Mar 2021 15:37:29
User entered '5'	System	12 Mar 2021 16:25:57
User entered '4'	System	26 Feb 2021 16:41:22
User entered '3'	System	18 Feb 2021 20:03:35
User entered '2'	System	25 Nov 2020 12:45:11
User entered '1'	System	28 Oct 2020 21:01:02

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:15:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered '15/Mar/2021 08:37'	System	15 Mar 2021 15:37:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:15:52

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.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:23:27
User entered 'I'	(b) (4), (b) (6)	15 Mar 2021 15:37:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'USA-US108-2020-MRNA-1273-P301000011'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'Yes (Y)'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	System	11 Mar 2021 14:13:06
Signature has been broken.	System	11 Mar 2021 14:13:06
User entered 'No (N)'	System	11 Mar 2021 14:13:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Yes (Y)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 18:26:17
Un-reviewed for Safety.	System	24 Mar 2021 18:25:23
Signature has been broken.	System	24 Mar 2021 18:25:23
User entered 'Yes (Y)'	System	24 Mar 2021 18:25:23
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'Yes (Y)'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	System	11 Mar 2021 14:13:06
Signature has been broken.	System	11 Mar 2021 14:13:06
User entered 'No (N)'	System	11 Mar 2021 14:13:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Yes (Y)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Joel'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Solis'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered '5201 N. 10th Street'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
Signature has been broken.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User entered '1020 Zinnia Ave' reason for change:	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
Data Entry Error	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered '5201 N. 10th Street'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Mcallen'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'TX'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'carmpa'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
Signature has been broken.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 20:03:38
Un-reviewed for Safety.	System	25 Nov 2020 12:45:11
User entered 'carmpa'	System	25 Nov 2020 12:45:11
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 12:45:01
Un-reviewed for Safety.	Joanna Gurrola Mahoney	12 Nov 2020 23:27:50
	(b) (4)	
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney	12 Nov 2020 23:27:50
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'carmpa'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 12:45:01
User entered 'US'	System	28 Oct 2020 21:01:02

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	22 Apr 2021 17:55:11
User entered '12'	System	15 Apr 2021 14:11:36
User entered '11'	System	07 Apr 2021 13:34:43
User entered '10'	System	31 Mar 2021 17:35:34
User entered '9'	System	24 Mar 2021 18:36:02
User entered '8'	System	24 Mar 2021 18:26:47
User entered '7'	System	19 Mar 2021 14:23:09
User entered '6'	System	15 Mar 2021 15:37:29
User entered '5'	System	12 Mar 2021 16:25:57
User entered '4'	System	26 Feb 2021 16:41:22
User entered '3'	System	18 Feb 2021 20:03:35
User entered '2'	System	25 Nov 2020 12:45:11
User entered '1'	System	28 Oct 2020 21:01:02

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:15:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered '19/Mar/2021 10:23'	System	19 Mar 2021 14:23:09

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:15:52

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.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:23:27
User entered 'I'	(b) (4), (b) (6)	19 Mar 2021 14:23:09

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'USA-US108-2020-MRNA-1273-P301000011'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'Yes (Y)'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	System	11 Mar 2021 14:13:06
Signature has been broken.	System	11 Mar 2021 14:13:06
User entered 'No (N)'	System	11 Mar 2021 14:13:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Yes (Y)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 18:26:17
Un-reviewed for Safety.	System	24 Mar 2021 18:25:23
Signature has been broken.	System	24 Mar 2021 18:25:23
User entered 'Yes (Y)'	System	24 Mar 2021 18:25:23
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'Yes (Y)'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	System	11 Mar 2021 14:13:06
Signature has been broken.	System	11 Mar 2021 14:13:06
User entered 'No (N)'	System	11 Mar 2021 14:13:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Yes (Y)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Joel'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Solis'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered '5201 N. 10th Street'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
Signature has been broken.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User entered '1020 Zinnia Ave' reason for change:	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
Data Entry Error	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered '5201 N. 10th Street'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Mcallen'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'TX'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'carmpa'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
Signature has been broken.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 20:03:38
Un-reviewed for Safety.	System	25 Nov 2020 12:45:11
User entered 'carmpa'	System	25 Nov 2020 12:45:11
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 12:45:01
Un-reviewed for Safety.	Joanna Gurrola Mahoney	12 Nov 2020 23:27:50
	(b) (4)	
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney	12 Nov 2020 23:27:50
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'carmpa'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 12:45:01
User entered 'US'	System	28 Oct 2020 21:01:02

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	22 Apr 2021 17:55:11
User entered '12'	System	15 Apr 2021 14:11:36
User entered '11'	System	07 Apr 2021 13:34:43
User entered '10'	System	31 Mar 2021 17:35:34
User entered '9'	System	24 Mar 2021 18:36:02
User entered '8'	System	24 Mar 2021 18:26:47
User entered '7'	System	19 Mar 2021 14:23:09
User entered '6'	System	15 Mar 2021 15:37:29
User entered '5'	System	12 Mar 2021 16:25:57
User entered '4'	System	26 Feb 2021 16:41:22
User entered '3'	System	18 Feb 2021 20:03:35
User entered '2'	System	25 Nov 2020 12:45:11
User entered '1'	System	28 Oct 2020 21:01:02

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 16:15:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered '24/Mar/2021 13:26'	System	24 Mar 2021 18:26:47

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 16:15:52

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.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 18:35:48
Un-reviewed for Safety.		24 Mar 2021 18:26:47
User entered '1' reason for change: New Information		24 Mar 2021 18:26:47
Reviewed for Safety.		19 Mar 2021 14:23:27
User entered '0'		19 Mar 2021 14:23:09

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'USA-US108-2020-MRNA-1273-P301000011'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'Yes (Y)'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	System	11 Mar 2021 14:13:06
Signature has been broken.	System	11 Mar 2021 14:13:06
User entered 'No (N)'	System	11 Mar 2021 14:13:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Yes (Y)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 18:26:17
Un-reviewed for Safety.	System	24 Mar 2021 18:25:23
Signature has been broken.	System	24 Mar 2021 18:25:23
User entered 'Yes (Y)'	System	24 Mar 2021 18:25:23
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'Yes (Y)'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	System	11 Mar 2021 14:13:06
Signature has been broken.	System	11 Mar 2021 14:13:06
User entered 'No (N)'	System	11 Mar 2021 14:13:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Yes (Y)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Joel'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Solis'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered '5201 N. 10th Street'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
Signature has been broken.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User entered '1020 Zinnia Ave' reason for change:	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
Data Entry Error	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered '5201 N. 10th Street'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Mcallen'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'TX'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'carmpa'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
Signature has been broken.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 20:03:38
Un-reviewed for Safety.	System	25 Nov 2020 12:45:11
User entered 'carmpa'	System	25 Nov 2020 12:45:11
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 12:45:01
Un-reviewed for Safety.	Joanna Gurrola Mahoney	12 Nov 2020 23:27:50
	(b) (4)	
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney	12 Nov 2020 23:27:50
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'carmpa'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 12:45:01
User entered 'US'	System	28 Oct 2020 21:01:02

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	22 Apr 2021 17:55:11
User entered '12'	System	15 Apr 2021 14:11:36
User entered '11'	System	07 Apr 2021 13:34:43
User entered '10'	System	31 Mar 2021 17:35:34
User entered '9'	System	24 Mar 2021 18:36:02
User entered '8'	System	24 Mar 2021 18:26:47
User entered '7'	System	19 Mar 2021 14:23:09
User entered '6'	System	15 Mar 2021 15:37:29
User entered '5'	System	12 Mar 2021 16:25:57
User entered '4'	System	26 Feb 2021 16:41:22
User entered '3'	System	18 Feb 2021 20:03:35
User entered '2'	System	25 Nov 2020 12:45:11
User entered '1'	System	28 Oct 2020 21:01:02

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 16:15:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered '24/Mar/2021 13:35'	System	24 Mar 2021 18:36:02

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 16:15:52

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)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:34:28
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered 'I'	(b) (4), (b) (6)	24 Mar 2021 18:36:02

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'USA-US108-2020-MRNA-1273-P301000011'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'Yes (Y)'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	System	11 Mar 2021 14:13:06
Signature has been broken.	System	11 Mar 2021 14:13:06
User entered 'No (N)'	System	11 Mar 2021 14:13:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Yes (Y)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 18:26:17
Un-reviewed for Safety.	System	24 Mar 2021 18:25:23
Signature has been broken.	System	24 Mar 2021 18:25:23
User entered 'Yes (Y)'	System	24 Mar 2021 18:25:23
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'Yes (Y)'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	System	11 Mar 2021 14:13:06
Signature has been broken.	System	11 Mar 2021 14:13:06
User entered 'No (N)'	System	11 Mar 2021 14:13:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Yes (Y)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Joel'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Solis'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered '5201 N. 10th Street'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
Signature has been broken.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User entered '1020 Zinnia Ave' reason for change:	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
Data Entry Error	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered '5201 N. 10th Street'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Mcallen'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'TX'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'carmpa'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
Signature has been broken.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 20:03:38
Un-reviewed for Safety.	System	25 Nov 2020 12:45:11
User entered 'carmpa'	System	25 Nov 2020 12:45:11
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 12:45:01
Un-reviewed for Safety.	Joanna Gurrola Mahoney	12 Nov 2020 23:27:50
	(b) (4)	
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney	12 Nov 2020 23:27:50
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'carmpa'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 12:45:01
User entered 'US'	System	28 Oct 2020 21:01:02

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	22 Apr 2021 17:55:11
User entered '12'	System	15 Apr 2021 14:11:36
User entered '11'	System	07 Apr 2021 13:34:43
User entered '10'	System	31 Mar 2021 17:35:34
User entered '9'	System	24 Mar 2021 18:36:02
User entered '8'	System	24 Mar 2021 18:26:47
User entered '7'	System	19 Mar 2021 14:23:09
User entered '6'	System	15 Mar 2021 15:37:29
User entered '5'	System	12 Mar 2021 16:25:57
User entered '4'	System	26 Feb 2021 16:41:22
User entered '3'	System	18 Feb 2021 20:03:35
User entered '2'	System	25 Nov 2020 12:45:11
User entered '1'	System	28 Oct 2020 21:01:02

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 16:15:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered '31/Mar/2021 10:35'	System	31 Mar 2021 17:35:34

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 16:15:52

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)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:34:28
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
User entered 'I'	(b) (4), (b) (6)	31 Mar 2021 17:35:34

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'USA-US108-2020-MRNA-1273-P301000011'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'Yes (Y)'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	System	11 Mar 2021 14:13:06
Signature has been broken.	System	11 Mar 2021 14:13:06
User entered 'No (N)'	System	11 Mar 2021 14:13:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Yes (Y)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 18:26:17
Un-reviewed for Safety.	System	24 Mar 2021 18:25:23
Signature has been broken.	System	24 Mar 2021 18:25:23
User entered 'Yes (Y)'	System	24 Mar 2021 18:25:23
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'Yes (Y)'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	System	11 Mar 2021 14:13:06
Signature has been broken.	System	11 Mar 2021 14:13:06
User entered 'No (N)'	System	11 Mar 2021 14:13:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Yes (Y)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Joel'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Solis'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered '5201 N. 10th Street'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
Signature has been broken.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User entered '1020 Zinnia Ave' reason for change:	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
Data Entry Error	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered '5201 N. 10th Street'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Mcallen'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'TX'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'carmpa'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
Signature has been broken.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 20:03:38
Un-reviewed for Safety.	System	25 Nov 2020 12:45:11
User entered 'carmpa'	System	25 Nov 2020 12:45:11
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 12:45:01
Un-reviewed for Safety.	Joanna Gurrola Mahoney	12 Nov 2020 23:27:50
	(b) (4)	
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney	12 Nov 2020 23:27:50
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'carmpa'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 12:45:01
User entered 'US'	System	28 Oct 2020 21:01:02

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	22 Apr 2021 17:55:11
User entered '12'	System	15 Apr 2021 14:11:36
User entered '11'	System	07 Apr 2021 13:34:43
User entered '10'	System	31 Mar 2021 17:35:34
User entered '9'	System	24 Mar 2021 18:36:02
User entered '8'	System	24 Mar 2021 18:26:47
User entered '7'	System	19 Mar 2021 14:23:09
User entered '6'	System	15 Mar 2021 15:37:29
User entered '5'	System	12 Mar 2021 16:25:57
User entered '4'	System	26 Feb 2021 16:41:22
User entered '3'	System	18 Feb 2021 20:03:35
User entered '2'	System	25 Nov 2020 12:45:11
User entered '1'	System	28 Oct 2020 21:01:02

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 16:15:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered '07/Apr/2021 13:34'	System	07 Apr 2021 13:34:43

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 16:15:52

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)
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 14:11:11
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:06:20
User entered 'I'	(b) (4), (b) (6)	07 Apr 2021 13:34:43

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'USA-US108-2020-MRNA-1273-P301000011'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'Yes (Y)'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	System	11 Mar 2021 14:13:06
Signature has been broken.	System	11 Mar 2021 14:13:06
User entered 'No (N)'	System	11 Mar 2021 14:13:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Yes (Y)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 18:26:17
Un-reviewed for Safety.	System	24 Mar 2021 18:25:23
Signature has been broken.	System	24 Mar 2021 18:25:23
User entered 'Yes (Y)'	System	24 Mar 2021 18:25:23
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'Yes (Y)'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	System	11 Mar 2021 14:13:06
Signature has been broken.	System	11 Mar 2021 14:13:06
User entered 'No (N)'	System	11 Mar 2021 14:13:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Yes (Y)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Joel'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Solis'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered '5201 N. 10th Street'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
Signature has been broken.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User entered '1020 Zinnia Ave' reason for change:	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
Data Entry Error	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered '5201 N. 10th Street'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Mcallen'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'TX'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'carmpa'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
Signature has been broken.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 20:03:38
Un-reviewed for Safety.	System	25 Nov 2020 12:45:11
User entered 'carmpa'	System	25 Nov 2020 12:45:11
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 12:45:01
Un-reviewed for Safety.	Joanna Gurrola Mahoney	12 Nov 2020 23:27:50
	(b) (4)	
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney	12 Nov 2020 23:27:50
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'carmpa'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 12:45:01
User entered 'US'	System	28 Oct 2020 21:01:02

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	22 Apr 2021 17:55:11
User entered '12'	System	15 Apr 2021 14:11:36
User entered '11'	System	07 Apr 2021 13:34:43
User entered '10'	System	31 Mar 2021 17:35:34
User entered '9'	System	24 Mar 2021 18:36:02
User entered '8'	System	24 Mar 2021 18:26:47
User entered '7'	System	19 Mar 2021 14:23:09
User entered '6'	System	15 Mar 2021 15:37:29
User entered '5'	System	12 Mar 2021 16:25:57
User entered '4'	System	26 Feb 2021 16:41:22
User entered '3'	System	18 Feb 2021 20:03:35
User entered '2'	System	25 Nov 2020 12:45:11
User entered '1'	System	28 Oct 2020 21:01:02

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (12)

Generated On: 09 Jun 2021 16:15:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '15/Apr/2021 14:11'	System	15 Apr 2021 14:11:36

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (12)

Generated On: 09 Jun 2021 16:15:52

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.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered 'I'	(b) (4), (b) (6)	15 Apr 2021 14:11:36

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'USA-US108-2020-MRNA-1273-P301000011'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'Yes (Y)'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	System	11 Mar 2021 14:13:06
Signature has been broken.	System	11 Mar 2021 14:13:06
User entered 'No (N)'	System	11 Mar 2021 14:13:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Yes (Y)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 18:26:17
Un-reviewed for Safety.	System	24 Mar 2021 18:25:23
Signature has been broken.	System	24 Mar 2021 18:25:23
User entered 'Yes (Y)'	System	24 Mar 2021 18:25:23
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'Yes (Y)'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	System	11 Mar 2021 14:13:06
Signature has been broken.	System	11 Mar 2021 14:13:06
User entered 'No (N)'	System	11 Mar 2021 14:13:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Yes (Y)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'No (N)'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Joel'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Solis'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered '5201 N. 10th Street'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
Signature has been broken.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User entered '1020 Zinnia Ave' reason for change:	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
Data Entry Error	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered '5201 N. 10th Street'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'Mcallen'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'TX'	System	28 Oct 2020 21:00:29

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:56:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:28:10
User entered 'carmpa'	System	12 Mar 2021 16:25:42
Un-reviewed for Safety.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
Signature has been broken.	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney	11 Mar 2021 23:25:13
	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 20:03:38
Un-reviewed for Safety.	System	25 Nov 2020 12:45:11
User entered 'carmpa'	System	25 Nov 2020 12:45:11
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 12:45:01
Un-reviewed for Safety.	Joanna Gurrola Mahoney	12 Nov 2020 23:27:50
	(b) (4)	
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney	12 Nov 2020 23:27:50
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 21:00:48
User entered 'carmpa'	System	28 Oct 2020 21:00:29

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Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:11:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 12:45:01
User entered 'US'	System	28 Oct 2020 21:01:02

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	22 Apr 2021 17:55:11
User entered '12'	System	15 Apr 2021 14:11:36
User entered '11'	System	07 Apr 2021 13:34:43
User entered '10'	System	31 Mar 2021 17:35:34
User entered '9'	System	24 Mar 2021 18:36:02
User entered '8'	System	24 Mar 2021 18:26:47
User entered '7'	System	19 Mar 2021 14:23:09
User entered '6'	System	15 Mar 2021 15:37:29
User entered '5'	System	12 Mar 2021 16:25:57
User entered '4'	System	26 Feb 2021 16:41:22
User entered '3'	System	18 Feb 2021 20:03:35
User entered '2'	System	25 Nov 2020 12:45:11
User entered '1'	System	28 Oct 2020 21:01:02

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (13)

Generated On: 09 Jun 2021 16:15:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered '22/Apr/2021 13:55'	System	22 Apr 2021 17:55:11

US3252553

Folder: SAE USA-US108-2020-MRNA-1273-P301000011

Form: Safety Report Form (13)

Generated On: 09 Jun 2021 16:15:52

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.	Joel Solis (b) (4)	22 Apr 2021 19:06:25
User entered 'I'	(b) (4), (b) (6)	22 Apr 2021 17:55:11