

US3362023 (Prod: Meridian Clinical Research-(Baton Rouge, Louisiana) - Platinum - PPDS)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:33:31

All time stamps listed in this document are displayed in GMT

US3362023

Form: Participant Creation

Data signed: (b) (4) 23 Apr 2021 23:54:00

Generated On: 11 Aug 2021 22:33:31

[Participant ID](#)

US3362023

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

US3362023

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 10 Apr 2021 00:11:39

Generated On: 11 Aug 2021 22:33:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3362023

Folder: Screening

Form: Demographics

Data signed: (b) (4) 10 Apr 2021 00:11:36

Generated On: 11 Aug 2021 22:33:31

Date of Birth (MMM yyyy)	(b) (6) 1964
Age	55
Age Units	YEARS
Age (Derived)	55
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 10 Apr 2021 00:11:36

Generated On: 11 Aug 2021 22:33:31

Date of Informed Consent (<i>dd MMM yyyy</i>)	03 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 10 Apr 2021 00:11:36

Generated On: 11 Aug 2021 22:33:31

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 10 Apr 2021 00:11:36

Generated On: 11 Aug 2021 22:33:31

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 10 Apr 2021 00:11:36

Generated On: 11 Aug 2021 22:33:31

Condition	DEPRESSION
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) 10 Apr 2021 00:11:36

Generated On: 11 Aug 2021 22:33:31

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 10 Apr 2021 00:11:36

Generated On: 11 Aug 2021 22:33:31

Condition	COSMETIC DERMAL INJECTION
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	True
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3362023

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 10 Apr 2021 00:11:39

Generated On: 11 Aug 2021 22:33:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	03 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:28 (24 HR)
Vital Signs Date and Time (derived)	03 AUG 2020 14:28
Height (<i>xxx.x</i>)	164 cm
Weight (<i>xxx.x</i>)	57.2 kg
BMI (<i>xxx.x</i>)	21.26710 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) 10 Apr 2021 00:11:39

Generated On: 11 Aug 2021 22:33:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 10 Apr 2021 00:11:36

Generated On: 11 Aug 2021 22:33:31

Date of assessment (*dd MMM yyyy*) 03 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 2015

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 10 Apr 2021 00:11:39

Generated On: 11 Aug 2021 22:33:31

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☐ No ☐

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☐

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☐ No ☐

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☐

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities) Yes ☐ No ☐

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☐

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☐

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☐

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☐

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ No ☐

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☐

Other Yes ☐ No ☐

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 10 Apr 2021 00:11:39

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:41:03

Generated On: 11 Aug 2021 22:33:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3362023

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 17:41:03

Generated On: 11 Aug 2021 22:33:31

What was the date of randomization? (dd MMM yyyy) 03 AUG 2020

What was the participant's randomization number? 100739

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 17:41:03

Generated On: 11 Aug 2021 22:33:31

Height	ND - Not Done
Weight	ND - Not Done

US3362023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:41:03

Generated On: 11 Aug 2021 22:33:31

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)	03 AUG 2020
Time of assessment (00:00-23:59)	14:30 (24 HR)
Vital Signs Date and Time (derived)	03 AUG 2020 14:30
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	98 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:41:03

Generated On: 11 Aug 2021 22:33:31

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 AUG 2020
Time of assessment (00:00-23:59)	16:04 (24 HR)
Vital Signs Date and Time (derived)	03 AUG 2020 16:04
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3362023

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:41:03

Generated On: 11 Aug 2021 22:33:31

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) 15 Feb 2021 17:41:03

Generated On: 11 Aug 2021 22:33:31

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) 03 AUG 2020

What was the treatment time? (00:00-23:59) 15:17 (24 HR)

Treatment Date and Time (derived) 03 AUG 2020 15:17

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:41:03

Generated On: 11 Aug 2021 22:33:31

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

03 AUG 2020

Collection time (00:00-23:59)

14:50 (24 HR)

Collection date and time (derived)

03 AUG 2020 14:50

US3362023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:41:03

Generated On: 11 Aug 2021 22:33:31

Collection date (dd MMM yyyy)			03 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:48	03 AUG 2020 14:48
Nasopharyngeal Swab 2	No		

US3362023

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:41:03

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 AUG 2020 15:50

PC Open Date & Time

03 AUG 2020 15:37

PC Close Date & Time

03 AUG 2020 18:07

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.1 °F

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

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

PC Time Stamp	03 AUG 2020 19:36
PC Open Date & Time	03 AUG 2020 19:02
PC Close Date & Time	04 AUG 2020 11:59

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

04 AUG 2020 14:14

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

05 AUG 2020 17:56

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 14:15

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

07 AUG 2020 18:03

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 16:22

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 03:03

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

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

03 AUG 2020 17:30

PC Open Date & Time

03 AUG 2020 15:37

PC Close Date & Time

03 AUG 2020 18:07

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 AUG 2020 19:36

PC Open Date & Time

03 AUG 2020 19:02

PC Close Date & Time

04 AUG 2020 11:59

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:33:31

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

04 AUG 2020 14:15

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:33:31

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

05 AUG 2020 17:57

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:33:31

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

06 AUG 2020 14:13

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 18:04

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:33:31

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

08 AUG 2020 16:22

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 7
Please record - PAIN AT INJECTION SITE.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any REDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - UNDERARM GLAND SWELLING OR TENDERNESS.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	10 AUG 2020 03:03
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

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 ☐

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

03 AUG 2020 15:37

PC Close Date & Time

03 AUG 2020 18:07

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

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 ☐

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

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

No ☒

Yes ☐

PC Time stamp	03 AUG 2020 19:37
PC Open Date & Time	03 AUG 2020 19:02
PC Close Date & Time	04 AUG 2020 11:59

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

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 ☒

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 14:15
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 17:57
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

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)

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 14:14
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

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 ☒

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 18:04
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

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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EAB) (1725)

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 16:22
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

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)

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 03:04
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3362023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:41:03

Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3362023

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:41:03

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:41:03

Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 17 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3362023

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:41:03

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:41:03

Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3362023

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:41:03

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:41:04

Generated On: 11 Aug 2021 22:33:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3362023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:41:04

Generated On: 11 Aug 2021 22:33:31

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)	31 AUG 2020
Time of assessment (00:00-23:59)	12:31 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 12:31
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3362023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:41:04

Generated On: 11 Aug 2021 22:33:31

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

US3362023

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:41:04

Generated On: 11 Aug 2021 22:33:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

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

US3362023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:41:04

Generated On: 11 Aug 2021 22:33:31

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

PATIENT REPORTED STRANGE TASTE IN MOUTH, NUMBNESS AND MILD SWELLING OF THE TONGUE WITH ONSET 1 HOUR POST INJECTION. SYMPTOMS LASTED 2 HOURS AND RESOLVED COMPLETELY WITHOUT MEDICATION OR INTERVENTION.

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? _____

US3362023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:41:04

Generated On: 11 Aug 2021 22:33:31

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

31 AUG 2020

Collection time (00:00-23:59)

12:44 (24 HR)

Collection date and time (derived)

31 AUG 2020 12:44

US3362023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:41:03

Generated On: 11 Aug 2021 22:33:31

Collection date (dd MMM yyyy)			31 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:46	31 AUG 2020 12:46
Nasopharyngeal Swab 2	No		

US3362023

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:41:04

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:41:03

Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362023

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:41:03

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:41:03

Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362023

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:41:03

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:41:03

Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362023

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:41:03

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:41:04

Generated On: 11 Aug 2021 22:33:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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	VISIT3

US3362023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:41:04

Generated On: 11 Aug 2021 22:33:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 SEP 2020
Time of assessment (00:00-23:59)	11:35 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 11:35
Temperature (xxx.x)	37.3 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3362023

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:41:04

Generated On: 11 Aug 2021 22:33:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

US3362023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:41:04

Generated On: 11 Aug 2021 22:33:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 SEP 2020
Collection time (00:00-23:59)	11:41 (24 HR)
Collection date and time (derived)	28 SEP 2020 11:41

US3362023

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:41:04

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 OCT 2020 07:05:51
Patient Cloud Open Date & Time	03 OCT 2020 00:01
Patient Cloud Close Date & Time	07 OCT 2020 23:59

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 OCT 2020 07:00:59

Patient Cloud Open Date & Time

10 OCT 2020 00:01

Patient Cloud Close Date & Time

14 OCT 2020 23:59

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 OCT 2020 05:43:46
Patient Cloud Open Date & Time	17 OCT 2020 00:01
Patient Cloud Close Date & Time	21 OCT 2020 23:59

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 OCT 2020 05:43:19
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 NOV 2020 05:41:29
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 NOV 2020 06:03:03

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	20 NOV 2020 12:04:17
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 NOV 2020 06:08:06
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 DEC 2020 04:23:46
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 DEC 2020 06:48:40
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 DEC 2020 06:54:38

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 DEC 2020 20:05:00
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 DEC 2020 06:01:03

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 JAN 2021 17:06:01
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 JAN 2021 06:28:33
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 JAN 2021 06:39:16

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 JAN 2021 06:35:40

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 FEB 2021 06:25:59

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 FEB 2021 06:38:06
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 FEB 2021 06:55:29
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 FEB 2021 12:08:18

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 MAR 2021 06:20:05
Patient Cloud Open Date & Time	03 MAR 2021 00:01
Patient Cloud Close Date & Time	07 MAR 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

10 MAR 2021 02:16:07

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 MAR 2021 00:40:52
Patient Cloud Open Date & Time	17 MAR 2021 00:01
Patient Cloud Close Date & Time	21 MAR 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 MAR 2021 06:26:55
Patient Cloud Open Date & Time	24 MAR 2021 00:01
Patient Cloud Close Date & Time	28 MAR 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 MAR 2021 06:00:42
Patient Cloud Open Date & Time	31 MAR 2021 00:01
Patient Cloud Close Date & Time	04 APR 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 APR 2021 16:07:31

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 APR 2021 06:03:09

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 06:08:24

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 APR 2021 14:09:47
Patient Cloud Open Date & Time	28 APR 2021 00:01
Patient Cloud Close Date & Time	02 MAY 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

Patient Cloud Open Date & Time

05 MAY 2021 00:01

Patient Cloud Close Date & Time

09 MAY 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

Patient Cloud Open Date & Time

12 MAY 2021 00:01

Patient Cloud Close Date & Time

16 MAY 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 MAY 2021 00:01

Patient Cloud Close Date & Time

23 MAY 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

Patient Cloud Open Date & Time

26 MAY 2021 00:01

Patient Cloud Close Date & Time

30 MAY 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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°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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

Patient Cloud Open Date & Time

02 JUN 2021 00:01

Patient Cloud Close Date & Time

06 JUN 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

Patient Cloud Open Date & Time

09 JUN 2021 00:01

Patient Cloud Close Date & Time

13 JUN 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

Patient Cloud Open Date & Time

16 JUN 2021 00:01

Patient Cloud Close Date & Time

20 JUN 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

Patient Cloud Open Date & Time

23 JUN 2021 00:01

Patient Cloud Close Date & Time

27 JUN 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

Patient Cloud Open Date & Time

30 JUN 2021 00:01

Patient Cloud Close Date & Time

04 JUL 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

Patient Cloud Open Date & Time

07 JUL 2021 00:01

Patient Cloud Close Date & Time

11 JUL 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

Patient Cloud Open Date & Time

14 JUL 2021 00:01

Patient Cloud Close Date & Time

18 JUL 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

Patient Cloud Open Date & Time

21 JUL 2021 00:01

Patient Cloud Close Date & Time

25 JUL 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

Patient Cloud Open Date & Time

28 JUL 2021 00:01

Patient Cloud Close Date & Time

01 AUG 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 369
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

Patient Cloud Open Date & Time

04 AUG 2021 00:01

Patient Cloud Close Date & Time

08 AUG 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

Patient Cloud Open Date & Time

11 AUG 2021 00:01

Patient Cloud Close Date & Time

15 AUG 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 AUG 2021 00:01

Patient Cloud Close Date & Time

22 AUG 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

Patient Cloud Open Date & Time

25 AUG 2021 00:01

Patient Cloud Close Date & Time

29 AUG 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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="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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

Patient Cloud Open Date & Time

01 SEP 2021 00:01

Patient Cloud Close Date & Time

05 SEP 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

Patient Cloud Open Date & Time

08 SEP 2021 00:01

Patient Cloud Close Date & Time

12 SEP 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

Patient Cloud Open Date & Time

15 SEP 2021 00:01

Patient Cloud Close Date & Time

19 SEP 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

Patient Cloud Open Date & Time

22 SEP 2021 00:01

Patient Cloud Close Date & Time

26 SEP 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

Patient Cloud Open Date & Time

29 SEP 2021 00:01

Patient Cloud Close Date & Time

03 OCT 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

Patient Cloud Open Date & Time

06 OCT 2021 00:01

Patient Cloud Close Date & Time

10 OCT 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

Patient Cloud Open Date & Time

13 OCT 2021 00:01

Patient Cloud Close Date & Time

17 OCT 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 OCT 2021 00:01

Patient Cloud Close Date & Time

24 OCT 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 OCT 2021 00:01

Patient Cloud Close Date & Time

31 OCT 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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="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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 NOV 2021 00:01

Patient Cloud Close Date & Time

07 NOV 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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°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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 NOV 2021 00:01

Patient Cloud Close Date & Time

14 NOV 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 NOV 2021 00:01

Patient Cloud Close Date & Time

21 NOV 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 NOV 2021 00:01

Patient Cloud Close Date & Time

28 NOV 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 DEC 2021 00:01

Patient Cloud Close Date & Time

05 DEC 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 DEC 2021 00:01

Patient Cloud Close Date & Time

12 DEC 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 DEC 2021 00:01

Patient Cloud Close Date & Time

19 DEC 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 509
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 DEC 2021 00:01

Patient Cloud Close Date & Time

26 DEC 2021 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 DEC 2021 00:01

Patient Cloud Close Date & Time

02 JAN 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 JAN 2022 00:01

Patient Cloud Close Date & Time

09 JAN 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 JAN 2022 00:01

Patient Cloud Close Date & Time

16 JAN 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 JAN 2022 00:01

Patient Cloud Close Date & Time

23 JAN 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 JAN 2022 00:01

Patient Cloud Close Date & Time

30 JAN 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 FEB 2022 00:01

Patient Cloud Close Date & Time

06 FEB 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 FEB 2022 00:01

Patient Cloud Close Date & Time

13 FEB 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 565
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 FEB 2022 00:01

Patient Cloud Close Date & Time

20 FEB 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 572
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 FEB 2022 00:01

Patient Cloud Close Date & Time

27 FEB 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 MAR 2022 00:01

Patient Cloud Close Date & Time

06 MAR 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 MAR 2022 00:01

Patient Cloud Close Date & Time

13 MAR 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 MAR 2022 00:01

Patient Cloud Close Date & Time

20 MAR 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 MAR 2022 00:01

Patient Cloud Close Date & Time

27 MAR 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 MAR 2022 00:01

Patient Cloud Close Date & Time

03 APR 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 APR 2022 00:01

Patient Cloud Close Date & Time

10 APR 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 APR 2022 00:01

Patient Cloud Close Date & Time

17 APR 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 APR 2022 00:01

Patient Cloud Close Date & Time

24 APR 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 APR 2022 00:01

Patient Cloud Close Date & Time

01 MAY 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 MAY 2022 00:01

Patient Cloud Close Date & Time

08 MAY 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 MAY 2022 00:01

Patient Cloud Close Date & Time

15 MAY 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 MAY 2022 00:01

Patient Cloud Close Date & Time

22 MAY 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 MAY 2022 00:01

Patient Cloud Close Date & Time

29 MAY 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 JUN 2022 00:01

Patient Cloud Close Date & Time

05 JUN 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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°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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 JUN 2022 00:01

Patient Cloud Close Date & Time

12 JUN 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 JUN 2022 00:01

Patient Cloud Close Date & Time

19 JUN 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 JUN 2022 00:01

Patient Cloud Close Date & Time

26 JUN 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 JUN 2022 00:01

Patient Cloud Close Date & Time

03 JUL 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 JUL 2022 00:01

Patient Cloud Close Date & Time

10 JUL 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 JUL 2022 00:01

Patient Cloud Close Date & Time

17 JUL 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 JUL 2022 00:01

Patient Cloud Close Date & Time

24 JUL 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 JUL 2022 00:01

Patient Cloud Close Date & Time

31 JUL 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 AUG 2022 00:01

Patient Cloud Close Date & Time

07 AUG 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 AUG 2022 00:01

Patient Cloud Close Date & Time

14 AUG 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 AUG 2022 00:01

Patient Cloud Close Date & Time

21 AUG 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 AUG 2022 00:01

Patient Cloud Close Date & Time

28 AUG 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 AUG 2022 00:01

Patient Cloud Close Date & Time

04 SEP 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 SEP 2022 00:01

Patient Cloud Close Date & Time

11 SEP 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 SEP 2022 00:01

Patient Cloud Close Date & Time

18 SEP 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 SEP 2022 00:01

Patient Cloud Close Date & Time

25 SEP 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 SEP 2022 00:01

Patient Cloud Close Date & Time

02 OCT 2022 23:59

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 OCT 2022 00:01

Patient Cloud Close Date & Time

09 OCT 2022 23:59

US3362023

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:33:31

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
Yes	No	27 FEB 2021 19:42:19

US3362023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 06 Mar 2021 04:14:30

Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362023

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 04:14:19

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362023

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Apr 2021 23:54:00

Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362023

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 23:54:00

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Apr 2021 23:54:00

Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362023

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 23:54:00

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362023

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Apr 2021 23:54:00

Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362023

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 23:54:00

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362023

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 23 Apr 2021 23:54:10

Generated On: 11 Aug 2021 22:33:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3362023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

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

US3362023

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Apr 2021 23:54:10

Generated On: 11 Aug 2021 22:33:31

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.

US3362023

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Apr 2021 23:54:10

Generated On: 11 Aug 2021 22:33:31

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 FEB 2021

Collection time (00:00-23:59)

12:38 (24 HR)

Collection date and time (derived)

22 FEB 2021 12:38

US3362023

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 23:54:10

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362023

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 23 Apr 2021 23:54:00

Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362023

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 23:54:00

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362023

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

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

US3362023

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3362023

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:33:31

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"/>

US3362023

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:33:31

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3362023

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

Form: Visit Date

Data signed: (b) (4) 23 Apr 2021 23:54:00

Generated On: 11 Aug 2021 22:33:31

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

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

Folder OID	UNBLND_DECIDE
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US3362023

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

Form: Unblinding

Data signed: (b) (4) 23 Apr 2021 23:54:00

Generated On: 11 Aug 2021 22:33:31

Date of updated informed consent (dd MMM yyyy) 25 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 25 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☐ Placebo ☐ Not Administered ☒

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3362023

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Apr 2021 23:54:00

Generated On: 11 Aug 2021 22:33:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 JAN 2021
Collection time (00:00-23:59)	13:05 (24 HR)
Collection date and time (derived)	25 JAN 2021 13:05

US3362023

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Apr 2021 23:54:00

Generated On: 11 Aug 2021 22:33:31

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

Collection date (dd MMM yyyy)	25 JAN 2021
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Collection time (00:00 - 23:59)	13:07
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Collection Date and Time (derived)	25 JAN 2021 13:07
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US3362023

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Mar 2021 22:08:35

Generated On: 11 Aug 2021 22:33:31

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3362023

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Mar 2021 22:08:35

Generated On: 11 Aug 2021 22:33:31

AEID

Adverse event

TONGUE SWELLING - POST
INJECTION ALLERGIC
REACTION

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)

03 AUG 2020

Start time (00:00-23:59)

16:20 (24 HR)

AE start date and time (derived)

03 AUG 2020 16:20

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

03 AUG 2020

End time (00:00-23:59)

18:20 (24 HR)

AE End Date and Time (derived)

03 AUG 2020 18:20

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 ☐

PRODUCTION RELEASE (v12.003

287 of 3235

EAB) (1725)

US3362023

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Mar 2021 22:08:35

Generated On: 11 Aug 2021 22:33:31

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 type="radio"/> Related <input checked="" 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)	

US3362023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Apr 2021 00:45:57

Generated On: 11 Aug 2021 22:33:31

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

Yes ☒

No ☐

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

US3362023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 00:45:57

Generated On: 11 Aug 2021 22:33:31

Name of Medication WELLBUTRIN

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

290 of 3235

US3362023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 00:45:57

Generated On: 11 Aug 2021 22:33:31

	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 2000
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"/>

US3362023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 00:45:57

Generated On: 11 Aug 2021 22:33:31

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3362023

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 23 Apr 2021 23:54:00

Generated On: 11 Aug 2021 22:33:31

Date of dosing discontinuation (dd MMM yyyy)	03 AUG 2020
--	-------------

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

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

US3362023 (Prod: Meridian Clinical Research-(Baton Rouge, Louisiana) - Platinum - PPDS)

US3362023

Form: Participant Creation

Generated On: 11 Aug 2021 22:33:31

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
User entered 'US3362023'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 19:09:43

US3362023

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:39
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	03 Aug 2020 20:34:38

US3362023

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:39
User entered '03 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 19:09:44

US3362023

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[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 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:39
User entered 'Clinic (Clinic)'	Crystal Rowell (b) (4)	03 Aug 2020 20:34:38

US3362023

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User entered 'SCRN'	System	03 Aug 2020 20:34:38

US3362023

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered (b) (6) 1964'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 19:09:45

US3362023

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered '55'	Crystal Rowell (b) (4)	03 Aug 2020 20:35:24

US3362023

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User entered 'YEARS'	System	03 Aug 2020 20:35:24

US3362023

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User entered '55'	System	03 Aug 2020 20:35:50

US3362023

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered 'Female (F)'	Crystal Rowell (b) (4)	03 Aug 2020 20:35:24

US3362023

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Aug 2020 20:35:32
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	03 Aug 2020 20:35:32
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	03 Aug 2020 20:35:24
	Crystal Rowell (b) (4)	03 Aug 2020 20:35:24
	(b) (4)	

US3362023

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered 'I'	Crystal Rowell (b) (4)	03 Aug 2020 20:35:24

US3362023

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered '0'	Crystal Rowell (b) (4)	03 Aug 2020 20:35:24

US3362023

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered '0'	Crystal Rowell (b) (4)	03 Aug 2020 20:35:24

US3362023

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered '0'	Crystal Rowell (b) (4)	03 Aug 2020 20:35:24

US3362023

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered '0'	Crystal Rowell (b) (4)	03 Aug 2020 20:35:24

US3362023

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered '0'	Crystal Rowell (b) (4)	03 Aug 2020 20:35:24

US3362023

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered empty.	Crystal Rowell (b) (4)	03 Aug 2020 20:35:24

US3362023

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered '0'	Crystal Rowell (b) (4)	03 Aug 2020 20:35:24

US3362023

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered '0'	Crystal Rowell (b) (4)	03 Aug 2020 20:35:24

US3362023

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:33:31

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered '03 Aug 2020'	Crystal Rowell (b) (4)	03 Aug 2020 20:35:50

US3362023

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User entered 'Aug 2020'	System	03 Aug 2020 20:35:50

US3362023

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User entered '2020'	System	03 Aug 2020 20:35:50

US3362023

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:33:31

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered 'Amendment 1 (1)'	Crystal Rowell (b) (4)	03 Aug 2020 20:35:50

US3362023

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	03 Aug 2020 20:35:50

US3362023

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered empty.	Crystal Rowell (b) (4)	03 Aug 2020 20:35:50

US3362023

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:33:31

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered empty.	Crystal Rowell (b) (4)	03 Aug 2020 20:35:50

US3362023

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:33:31

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered 'No (N)'	Crystal Rowell (b) (4)	03 Aug 2020 20:35:50

US3362023

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:33:31

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 19:09:44

US3362023

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:33:31

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User entered 'I'	System	03 Aug 2020 20:35:54

US3362023

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	03 Aug 2020 20:35:54

US3362023

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:33:31

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	10 Aug 2020 18:08:47

US3362023

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:33:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 18:11:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 18:11:14
Data point term sent to Coder	System	10 Aug 2020 18:09:52
User entered 'Depression'	Crystal Rowell (b) (4)	10 Aug 2020 18:09:12

US3362023

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered 'un UNK 2000'	Crystal Rowell (b) (4)	10 Aug 2020 18:09:12

US3362023

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered '0'	Crystal Rowell (b) (4)	10 Aug 2020 18:09:12

US3362023

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:33:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	10 Aug 2020 18:09:12

US3362023

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered empty.	Crystal Rowell (b) (4)	10 Aug 2020 18:09:12

US3362023

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:33:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered '0'	Crystal Rowell (b) (4)	10 Aug 2020 18:09:12

US3362023

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User entered 'Jan 2000'	System	10 Aug 2020 18:09:12

US3362023

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User entered '2000'	System	10 Aug 2020 18:09:12

US3362023

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User entered empty.	System	10 Aug 2020 18:09:12

US3362023

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User entered empty.	System	10 Aug 2020 18:09:12

US3362023

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:33:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 14:04:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 14:04:33
Data point term sent to Coder	System	17 Sep 2020 14:03:50
User entered 'Post menopausal'	(b) (4), (b) (6)	17 Sep 2020 14:03:18

US3362023

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:03:18

US3362023

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 14:03:18

US3362023

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:33:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 14:03:18

US3362023

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 14:03:18

US3362023

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:33:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 14:03:18

US3362023

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User entered 'Jan 2015'	System	17 Sep 2020 14:03:18

US3362023

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User entered '2015'	System	17 Sep 2020 14:03:18

US3362023

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User entered empty.	System	17 Sep 2020 14:03:18

US3362023

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User entered empty.	System	17 Sep 2020 14:03:18

US3362023

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:33:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin and subcutaneous tissue therapeutic procedures NEC, PT: Dermal filler injection, LLT: Dermal filler injection - version MedDRA\\23.0.	Coder Import (b) (4)	30 Mar 2021 21:44:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Mar 2021 21:44:12
Data point term sent to Coder	System	30 Mar 2021 21:42:46
User entered 'COSMETIC Dermal INJECTION' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	30 Mar 2021 21:42:31
Data point term sent to Coder	System	30 Mar 2021 21:33:34
User entered 'cosmetic injection'	Crystal Rowell (b) (4)	30 Mar 2021 21:32:49

US3362023

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered empty.	Crystal Rowell (b) (4)	30 Mar 2021 21:32:49

US3362023

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered 'I'	Crystal Rowell (b) (4)	30 Mar 2021 21:32:49

US3362023

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:33:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	(b) (4) System	30 Mar 2021 21:32:56
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	30 Mar 2021 21:32:49
User entered 'No (N)'	Crystal Rowell (b) (4) (b) (4)	30 Mar 2021 21:32:49

US3362023

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered empty.	Crystal Rowell (b) (4)	30 Mar 2021 21:32:49

US3362023

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:33:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Crystal Rowell (b) (4)	30 Mar 2021 21:32:56
User entered '0'	(b) (4)	
	Crystal Rowell (b) (4)	30 Mar 2021 21:32:49
	(b) (4)	

US3362023

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User entered empty.	System	30 Mar 2021 21:32:49

US3362023

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User entered empty.	System	30 Mar 2021 21:32:49

US3362023

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User entered empty.	System	30 Mar 2021 21:32:49

US3362023

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User entered empty.	System	30 Mar 2021 21:32:49

US3362023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:39
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	10 Aug 2020 18:10:39

US3362023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:39
User entered '03 Aug 2020'	Crystal Rowell (b) (4)	10 Aug 2020 18:10:39

US3362023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:39
User entered '14:28' reason for change: Data Entry Error	(b) (4)	12 Nov 2020 21:38:34
User entered '14:30'	Alexandra Caillouet (b) (4)	10 Aug 2020 18:10:39
	(b) (4)	

US3362023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User entered '03 Aug 2020 14:28'	System	12 Nov 2020 21:38:34
User entered '03 Aug 2020 14:30'	System	10 Aug 2020 18:10:39

US3362023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:39
User entered '164' cm	Crystal Rowell (b) (4)	10 Aug 2020 18:10:39
DataPoint set to visible.	System	03 Aug 2020 20:35:54

US3362023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:39
User entered '57.2' kg	Crystal Rowell (b) (4)	10 Aug 2020 18:10:39
DataPoint set to visible.	System	03 Aug 2020 20:35:54

US3362023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
Amendment Manager: User entered '21.26710'	System	16 Sep 2020 23:41:34
User entered '21.3'	System	10 Aug 2020 18:10:39
DataPoint set to visible.	System	03 Aug 2020 20:35:54

US3362023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User entered 'kg/m2'	System	10 Aug 2020 18:10:39
DataPoint set to visible.	System	03 Aug 2020 20:35:54

US3362023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:39
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 06:32:00
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 13:23:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:23:17
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 10:06:30
User entered '37.1' C	Crystal Rowell (b) (4) (b) (4)	10 Aug 2020 18:10:39

US3362023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:39
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:23:17
User entered 'Oral (Oral)'	Crystal Rowell (b) (4)	10 Aug 2020 18:10:39

US3362023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:39
User entered empty.	Crystal Rowell (b) (4)	10 Aug 2020 18:10:39

US3362023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:23:17
User entered '98'	Crystal Rowell (b) (4)	10 Aug 2020 18:10:39

US3362023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User entered 'bpm'	System	10 Aug 2020 18:10:39

US3362023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:39
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:23:17
User entered '18'	Crystal Rowell (b) (4)	10 Aug 2020 18:10:39
	(b) (4)	

US3362023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User entered 'breaths/min'	System	10 Aug 2020 18:10:39

US3362023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:39
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:23:17
User entered '135'	Crystal Rowell (b) (4)	10 Aug 2020 18:10:39
	(b) (4)	

US3362023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User entered 'mmHg'	System	10 Aug 2020 18:10:39

US3362023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:23:17
User entered '76'	Crystal Rowell (b) (4)	10 Aug 2020 18:10:39

US3362023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User entered 'mmHg'	System	10 Aug 2020 18:10:39

US3362023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39

US3362023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39

US3362023

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Amy Thomassie (b) (4)	07 Sep 2020 15:02:57
User entered 'No (N)' reason for change: Data Entry Error	Amy Thomassie (b) (4)	06 Sep 2020 19:20:35
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	10 Aug 2020 18:13:31

US3362023

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:39
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	08 Sep 2020 10:08:27
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	07 Sep 2020 15:02:57
User entered '03 Aug 2020' reason for change: Data Entry Error	Amy Thomassie (b) (4) (b) (4)	07 Sep 2020 15:02:57
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	06 Sep 2020 19:20:35
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4) (b) (4)	06 Sep 2020 19:20:35
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	31 Aug 2020 20:33:17
User entered '03 Aug 2020'	Crystal Rowell (b) (4) (b) (4)	10 Aug 2020 18:13:31

US3362023

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:33:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered '03 Aug 2020'	Crystal Rowell (b) (4)	10 Aug 2020 18:14:14

US3362023

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered 'No (N)'	Crystal Rowell (b) (4)	10 Aug 2020 18:14:14

US3362023

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:33:31

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Sep 2020 07:15:26
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' answered with 'ecrf has been updated' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 14:03:59
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 08:53:46
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Crystal Rowell (b) (4) (b) (4)	10 Aug 2020 18:14:14

US3362023

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:33:31

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered empty.	Crystal Rowell (b) (4)	10 Aug 2020 18:14:14

US3362023

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered empty.	Crystal Rowell (b) (4)	10 Aug 2020 18:14:14

US3362023

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:33:31

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered '0'	Crystal Rowell (b) (4)	10 Aug 2020 18:14:14

US3362023

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered 'un UNK 2015'	Crystal Rowell (b) (4)	10 Aug 2020 18:14:14

US3362023

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:33:31

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:36
User entered '0'	Crystal Rowell (b) (4)	10 Aug 2020 18:14:14

US3362023

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

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 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:39
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	10 Aug 2020 18:19:49

US3362023

Folder: Screening

Form: Risk of Exposure

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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 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:39
User entered 'No (N)'	Crystal Rowell (b) (4)	10 Aug 2020 18:19:49

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Folder: Screening

Form: Risk of Exposure

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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 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:39
User entered 'No (N)'	Crystal Rowell (b) (4)	10 Aug 2020 18:19:49

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Folder: Screening

Form: Risk of Exposure

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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 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:39
User entered 'No (N)'	Crystal Rowell (b) (4)	10 Aug 2020 18:19:49

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Folder: Screening

Form: Risk of Exposure

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[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 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:39
User entered 'No (N)'	Crystal Rowell (b) (4)	10 Aug 2020 18:19:49

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Folder: Screening

Form: Risk of Exposure

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[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 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:39
User entered 'No (N)'	Crystal Rowell (b) (4)	10 Aug 2020 18:19:49

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:39
User entered 'No (N)'	Crystal Rowell (b) (4)	10 Aug 2020 18:19:49

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:39
User entered 'No (N)'	Crystal Rowell (b) (4)	10 Aug 2020 18:19:49

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Folder: Screening

Form: Risk of Exposure

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[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 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:39
User entered 'No (N)'	Crystal Rowell (b) (4)	10 Aug 2020 18:19:49

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Folder: Screening

Form: Risk of Exposure

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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 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:39
User entered 'No (N)'	Crystal Rowell (b) (4)	10 Aug 2020 18:19:49

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Folder: Screening

Form: Risk of Exposure

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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 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:39
User entered 'No (N)'	Crystal Rowell (b) (4)	10 Aug 2020 18:19:49

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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:39
User entered 'No (N)'	Crystal Rowell (b) (4)	10 Aug 2020 18:19:49

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:39
User entered empty.	Crystal Rowell (b) (4)	10 Aug 2020 18:19:49

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:39
User entered '0'	Crystal Rowell (b) (4)	10 Aug 2020 18:19:49

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:39
User entered '0'	Crystal Rowell (b) (4)	10 Aug 2020 18:19:49

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

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 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:39
User entered '0'	Crystal Rowell (b) (4)	10 Aug 2020 18:19:49

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

[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 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:39
User entered '0'	Crystal Rowell (b) (4)	10 Aug 2020 18:19:49

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

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 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:39
User entered '0'	Crystal Rowell (b) (4)	10 Aug 2020 18:19:49

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:39
User entered 'I'	Crystal Rowell (b) (4)	10 Aug 2020 18:19:49

US3362023

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:39
User entered '0'	Crystal Rowell (b) (4)	10 Aug 2020 18:19:49

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:38:39
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:11:39
User entered empty.	Crystal Rowell (b) (4)	10 Aug 2020 18:19:49

US3362023

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	03 Aug 2020 20:36:10

US3362023

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered '03 Aug 2020'	Crystal Rowell (b) (4)	03 Aug 2020 20:36:10

US3362023

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[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 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Clinic (Clinic)'	Crystal Rowell (b) (4)	03 Aug 2020 20:36:10

US3362023

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered 'VISIT1'	System	03 Aug 2020 20:36:10

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered '03 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 20:04:13

US3362023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:33:31

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 01:48:07
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:48:07
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	03 Aug 2020 20:04:13
User entered '100739' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 20:04:13

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 20:04:13

US3362023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:33:31

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 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'No (N)'	Crystal Rowell (b) (4)	03 Aug 2020 20:36:22

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:33:31

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 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'No (N)'	Crystal Rowell (b) (4)	03 Aug 2020 20:36:22

US3362023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'No (N)'	Crystal Rowell (b) (4)	03 Aug 2020 20:36:22

US3362023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:33:31

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'No (N)'	Crystal Rowell (b) (4)	03 Aug 2020 20:36:22

US3362023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:33:31

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'No (N)'	Crystal Rowell (b) (4)	03 Aug 2020 20:36:22

US3362023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:33:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 06:32:06
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 13:24:16
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:24:07
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 10:06:39
User entered '164' cm	Crystal Rowell (b) (4) (b) (4)	10 Aug 2020 18:23:02

US3362023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:33:31

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:24:07
User entered '57.2' kg	Crystal Rowell (b) (4)	10 Aug 2020 18:23:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:33:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 06:32:06
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 13:24:16
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:24:07
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 10:06:39
User entered '164' cm	Crystal Rowell (b) (4) (b) (4)	10 Aug 2020 18:23:02

US3362023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:33:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:24:07
User entered '57.2' kg	Crystal Rowell (b) (4)	10 Aug 2020 18:23:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User accepted default value 'Pre-Dose (PREDOSE)'	Crystal Rowell (b) (4) (b) (4)	10 Aug 2020 18:23:02

US3362023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	10 Aug 2020 18:23:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered '03 Aug 2020'	Crystal Rowell (b) (4)	10 Aug 2020 18:23:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered '14:30'	Crystal Rowell (b) (4)	10 Aug 2020 18:23:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered '03 Aug 2020 14:30'	System	10 Aug 2020 18:23:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered '37.1' C	Crystal Rowell (b) (4)	10 Aug 2020 18:23:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Oral (Oral)'	Crystal Rowell (b) (4)	10 Aug 2020 18:23:02

US3362023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered empty.	Crystal Rowell (b) (4)	10 Aug 2020 18:23:02

US3362023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered '98'	Crystal Rowell (b) (4)	10 Aug 2020 18:23:02

US3362023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered 'bpm'	System	10 Aug 2020 18:23:02

US3362023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered '16'	Crystal Rowell (b) (4)	10 Aug 2020 18:23:02

US3362023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered 'breaths/min'	System	10 Aug 2020 18:23:02

US3362023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered '135'	Crystal Rowell (b) (4)	10 Aug 2020 18:23:02

US3362023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered 'mmHg'	System	10 Aug 2020 18:23:02

US3362023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered '76'	Crystal Rowell (b) (4)	10 Aug 2020 18:23:02

US3362023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered 'mmHg'	System	10 Aug 2020 18:23:02

US3362023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:33:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 06:32:06
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 13:24:16
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:24:07
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 10:06:39
User entered '164' cm	Crystal Rowell (b) (4) (b) (4)	10 Aug 2020 18:23:02

US3362023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:33:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:24:07
User entered '57.2' kg	Crystal Rowell (b) (4)	10 Aug 2020 18:23:02

US3362023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User accepted default value 'Post-Dose (POSTDOSE)'	Crystal Rowell (b) (4) (b) (4)	10 Aug 2020 18:23:02

US3362023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	10 Aug 2020 18:23:02

US3362023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered '03 Aug 2020'	Crystal Rowell (b) (4)	10 Aug 2020 18:23:02

US3362023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered '16:04' reason for change: Data Entry Error	(b) (4)	12 Nov 2020 23:17:02
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	Alexandra Caillouet (b) (4), (b) (6)	17 Aug 2020 09:28:03
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Per protocol, vitals taken after 30 mins.' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 13:54:30
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		10 Aug 2020 18:23:02
User entered '16:06'	Crystal Rowell (b) (4)	10 Aug 2020 18:23:02
	(b) (4)	

US3362023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered '03 Aug 2020 16:04'	System	12 Nov 2020 23:17:02
User entered '03 Aug 2020 16:06'	System	10 Aug 2020 18:23:02

US3362023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered '36.7' C	Crystal Rowell (b) (4)	10 Aug 2020 18:23:02

US3362023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Oral (Oral)'	Crystal Rowell (b) (4)	10 Aug 2020 18:23:02

US3362023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered empty.	Crystal Rowell (b) (4)	10 Aug 2020 18:23:02

US3362023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered '74'	Crystal Rowell (b) (4)	10 Aug 2020 18:23:02

US3362023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered 'bpm'	System	10 Aug 2020 18:23:02

US3362023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered '16'	Crystal Rowell (b) (4)	10 Aug 2020 18:23:02

US3362023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered 'breaths/min'	System	10 Aug 2020 18:23:02

US3362023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered '140'	Crystal Rowell (b) (4)	10 Aug 2020 18:23:02

US3362023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered 'mmHg'	System	10 Aug 2020 18:23:02

US3362023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered '82'	Crystal Rowell (b) (4)	10 Aug 2020 18:23:02

US3362023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered 'mmHg'	System	10 Aug 2020 18:23:02

US3362023

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	07 Sep 2020 15:03:13
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	10 Aug 2020 18:36:04
	(b) (4)	

US3362023

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	07 Sep 2020 15:03:13
User entered '03 Aug 2020'	Crystal Rowell (b) (4)	10 Aug 2020 18:36:04

US3362023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	03 Aug 2020 20:37:02

US3362023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered empty.	Crystal Rowell (b) (4)	03 Aug 2020 20:37:02

US3362023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

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 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered empty.	Crystal Rowell (b) (4)	03 Aug 2020 20:37:02

US3362023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered 'MRNA-1273 OR PLACEBO'	System	03 Aug 2020 20:37:02

US3362023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered '03 Aug 2020'	Crystal Rowell (b) (4)	03 Aug 2020 20:37:02

US3362023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered '15:17'	Crystal Rowell (b) (4)	03 Aug 2020 20:37:02

US3362023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered '03 Aug 2020 15:17'	System	03 Aug 2020 20:37:02

US3362023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Left Arm (LEFT ARM)'	Crystal Rowell (b) (4)	03 Aug 2020 20:37:02

US3362023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered 'ONCE'	System	03 Aug 2020 20:37:02

US3362023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered 'INTRAMUSCULAR'	System	03 Aug 2020 20:37:02

US3362023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	10 Aug 2020 18:36:30

US3362023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered '03 Aug 2020'	Crystal Rowell (b) (4)	10 Aug 2020 18:36:30

US3362023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered '14:50'	Crystal Rowell (b) (4)	10 Aug 2020 18:36:30

US3362023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered '03 Aug 2020 14:50'	System	10 Aug 2020 18:36:30

US3362023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:33:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	(b) (4)	10 Aug 2020 18:37:41
Query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' answered by data change (Site from System).	System	10 Aug 2020 18:37:41
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Aug 2020 18:37:41
User entered '03 Aug 2020' reason for change: Data Entry Error	Crystal Rowell (b) (4)	10 Aug 2020 18:37:41
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	10 Aug 2020 18:37:07
User opened query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	10 Aug 2020 18:37:07
User entered '03 Aug ' (non-conformant).	System	10 Aug 2020 18:37:07
	Crystal Rowell (b) (4)	10 Aug 2020 18:37:07
	(b) (4)	

US3362023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:33:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Crystal Rowell (b) (4) (b) (4)	10 Aug 2020 18:37:07

US3362023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:33:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	10 Aug 2020 18:37:07

US3362023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:33:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered '14:48'	Crystal Rowell (b) (4)	10 Aug 2020 18:37:07

US3362023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered '03 Aug 2020 14:48'	System	10 Aug 2020 18:37:41
User entered '03 Aug 14:48' (non-conformant).	System	10 Aug 2020 18:37:07

US3362023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:33:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Crystal Rowell (b) (4) (b) (4)	10 Aug 2020 18:37:07

US3362023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:33:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'No (N)'	Crystal Rowell (b) (4)	10 Aug 2020 18:37:07

US3362023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:33:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered empty.	Crystal Rowell (b) (4)	10 Aug 2020 18:37:07

US3362023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered empty.	System	10 Aug 2020 18:37:07

US3362023

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	10 Aug 2020 18:37:46

US3362023

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered 'I'	System	10 Aug 2020 18:37:46

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-03T15:50:31', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'f68eddee-06e3-456c-a5ad-208db145b5af' User entered 'Yes (Y)'	System	03 Aug 2020 20:50:54
	System	03 Aug 2020 20:50:54

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-03T15:50:37', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'f68eddee-06e3-456c-a5ad-208db145b5af' User entered '98.1'	System	03 Aug 2020 20:50:54
	System	03 Aug 2020 20:50:54

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-03T15:50:43', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'f68eddee-06e3-456c-a5ad-208db145b5af' User entered 'No (N)'	System	03 Aug 2020 20:50:54
	System	03 Aug 2020 20:50:54

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-03T15:50:51', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'f68eddee-06e3-456c-a5ad-208db145b5af' User entered '03 Aug 2020 15:50'	System	03 Aug 2020 20:50:54
	System	03 Aug 2020 20:50:54

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '03 Aug 2020 15:37'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '03 Aug 2020 18:07'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-03T19:16:19', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '0495dee9-3363-41a6-9a29-34ce0ac27d1f' User entered 'Yes (Y)'	System	04 Aug 2020 00:36:32
	System	04 Aug 2020 00:36:32

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-03T19:16:31', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '0495dee9-3363-41a6-9a29-34ce0ac27d1f' User entered '98.1'	System	04 Aug 2020 00:36:32
	System	04 Aug 2020 00:36:32

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-03T19:36:20', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '0495dee9-3363-41a6-9a29-34ce0ac27d1f' User entered 'No (N)'	System	04 Aug 2020 00:36:32
	System	04 Aug 2020 00:36:32

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-03T19:36:29', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '0495dee9-3363-41a6-9a29-34ce0ac27d1f' User entered '03 Aug 2020 19:36'	System	04 Aug 2020 00:36:32
	System	04 Aug 2020 00:36:32

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '03 Aug 2020 19:02'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered 'Day 2'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:33:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-04T14:14:44', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'bc4541db-8fd2-4be9-aced-2526e75e0106'	System	04 Aug 2020 19:15:01
User entered 'Yes (Y)'	System	04 Aug 2020 19:15:01

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-04T14:14:50', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'bc4541db-8fd2-4be9-aced-2526e75e0106'	System	04 Aug 2020 19:15:01
User entered '98.6'	System	04 Aug 2020 19:15:01

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-04T14:14:53', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'bc4541db-8fd2-4be9-aced-2526e75e0106'	System	04 Aug 2020 19:15:01
User entered 'No (N)'	System	04 Aug 2020 19:15:01

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-04T14:14:58', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'bc4541db-8fd2-4be9-aced-2526e75e0106'	System	04 Aug 2020 19:15:01
User entered '04 Aug 2020 14:14'	System	04 Aug 2020 19:15:01

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered 'Day 3'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:33:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-05T17:56:36', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '94f3d16f-ef20-45b9-a067-b93de3a2f246'	System	05 Aug 2020 22:56:51
User entered 'Yes (Y)'	System	05 Aug 2020 22:56:51

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-05T17:56:41', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '94f3d16f-ef20-45b9-a067-b93de3a2f246' User entered '98.7'	System	05 Aug 2020 22:56:51
	System	05 Aug 2020 22:56:51

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-05T17:56:45', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '94f3d16f-ef20-45b9-a067-b93de3a2f246'	System	05 Aug 2020 22:56:51
User entered 'No (N)'	System	05 Aug 2020 22:56:51

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-05T17:56:50', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '94f3d16f-ef20-45b9-a067-b93de3a2f246'	System	05 Aug 2020 22:56:51
User entered '05 Aug 2020 17:56'	System	05 Aug 2020 22:56:51

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered 'Day 4'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:33:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-06T14:14:51', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '451c7675-9d8d-456d-a131-3ea47afc9c10'	System	06 Aug 2020 19:15:07
User entered 'Yes (Y)'	System	06 Aug 2020 19:15:07

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-06T14:14:57', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '451c7675-9d8d-456d-a131-3ea47afc9c10' User entered '98.8'	System	06 Aug 2020 19:15:07
	System	06 Aug 2020 19:15:07

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-06T14:15:02', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '451c7675-9d8d-456d-a131-3ea47afc9c10'	System	06 Aug 2020 19:15:07
User entered 'No (N)'	System	06 Aug 2020 19:15:07

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-06T14:15:05', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '451c7675-9d8d-456d-a131-3ea47afc9c10' User entered '06 Aug 2020 14:15'	System	06 Aug 2020 19:15:07
	System	06 Aug 2020 19:15:07

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered 'Day 5'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:33:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-07T18:03:38', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'a3d22407-ae11-4283-bcd6-9ce72485f8d2'	System	07 Aug 2020 23:03:54
User entered 'Yes (Y)'	System	07 Aug 2020 23:03:54

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-07T18:03:46', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'a3d22407-ae11-4283-bcd6-9ce72485f8d2'	System	07 Aug 2020 23:03:54
User entered '98.6'	System	07 Aug 2020 23:03:54

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-07T18:03:49', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'a3d22407-ae11-4283-bcd6-9ce72485f8d2'	System	07 Aug 2020 23:03:54
User entered 'No (N)'	System	07 Aug 2020 23:03:54

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-07T18:03:52', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'a3d22407-ae11-4283-bcd6-9ce72485f8d2'	System	07 Aug 2020 23:03:54
User entered '07 Aug 2020 18:03'	System	07 Aug 2020 23:03:54

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered 'Day 6'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:33:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-08T16:21:55', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '95a6b4c0-b58e-488b-b866-c14acb740a2e' User entered 'Yes (Y)'	System	08 Aug 2020 21:22:06
	System	08 Aug 2020 21:22:06

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-08T16:21:59', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '95a6b4c0-b58e-488b-b866-c14acb740a2e' User entered '98.1'	System	08 Aug 2020 21:22:06
	System	08 Aug 2020 21:22:06

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-08T16:22:02', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '95a6b4c0-b58e-488b-b866-c14acb740a2e' User entered 'No (N)'	System	08 Aug 2020 21:22:06
	System	08 Aug 2020 21:22:06

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-08T16:22:05', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '95a6b4c0-b58e-488b-b866-c14acb740a2e' User entered '08 Aug 2020 16:22'	System	08 Aug 2020 21:22:06
	System	08 Aug 2020 21:22:06

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered 'Day 7'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:33:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-10T03:03:24', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'dd364bf1-5bd3-4272-a407-c4f225db34bf' User entered 'Yes (Y)'	System	10 Aug 2020 08:03:40
	System	10 Aug 2020 08:03:40

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-10T03:03:32', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'dd364bf1-5bd3-4272-a407-c4f225db34bf' User entered '98.4'	System	10 Aug 2020 08:03:40
	System	10 Aug 2020 08:03:40

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-10T03:03:35', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'dd364bf1-5bd3-4272-a407-c4f225db34bf' User entered 'No (N)'	System	10 Aug 2020 08:03:40
	System	10 Aug 2020 08:03:40

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-10T03:03:38', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'dd364bf1-5bd3-4272-a407-c4f225db34bf' User entered '10 Aug 2020 03:03'	System	10 Aug 2020 08:03:40
	System	10 Aug 2020 08:03:40

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-03T17:30:01', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '54a1b049-2c92-4aed-9763-587b714f34ed' User entered 'None (1)'	System	03 Aug 2020 22:30:20
	System	03 Aug 2020 22:30:20

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-03T17:30:04', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '54a1b049-2c92-4aed-9763-587b714f34ed' User entered 'No (N)'	System	03 Aug 2020 22:30:20
	System	03 Aug 2020 22:30:20

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-03T17:30:07', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '54a1b049-2c92-4aed-9763-587b714f34ed' User entered 'No (N)'	System	03 Aug 2020 22:30:20
	System	03 Aug 2020 22:30:20

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-03T17:30:10', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '54a1b049-2c92-4aed-9763-587b714f34ed' User entered 'None (1)'	System	03 Aug 2020 22:30:20
	System	03 Aug 2020 22:30:20

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-03T17:30:18', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '54a1b049-2c92-4aed-9763-587b714f34ed' User entered '03 Aug 2020 17:30'	System	03 Aug 2020 22:30:20
	System	03 Aug 2020 22:30:20

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '03 Aug 2020 15:37'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '03 Aug 2020 18:07'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-03T19:36:41', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '64617ed6-7094-44c4-9c51-e0fbe6799895'	System	04 Aug 2020 00:36:59
User entered 'Does not interfere with activity (2)'	System	04 Aug 2020 00:36:59

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-03T19:36:46', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '64617ed6-7094-44c4-9c51-e0fbe6799895' User entered 'No (N)'	System	04 Aug 2020 00:36:59
	System	04 Aug 2020 00:36:59

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-03T19:36:48', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '64617ed6-7094-44c4-9c51-e0fbe6799895' User entered 'No (N)'	System	04 Aug 2020 00:36:59
	System	04 Aug 2020 00:36:59

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-03T19:36:51', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '64617ed6-7094-44c4-9c51-e0fbe6799895'	System	04 Aug 2020 00:36:59
User entered 'None (1)'	System	04 Aug 2020 00:36:59

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-03T19:36:56', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '64617ed6-7094-44c4-9c51-e0fbe6799895' User entered '03 Aug 2020 19:36'	System	04 Aug 2020 00:36:59
	System	04 Aug 2020 00:36:59

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '03 Aug 2020 19:02'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered 'Day 2'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-04T14:15:10', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '0408e749-b5b6-4f7c-a163-324eff3e5e4e'	System	04 Aug 2020 19:15:29
User entered 'Does not interfere with activity (2)'	System	04 Aug 2020 19:15:29

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:33:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-04T14:15:14', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '0408e749-b5b6-4f7c-a163-324eff3e5e4e' User entered 'No (N)'	System	04 Aug 2020 19:15:29
	System	04 Aug 2020 19:15:29

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-04T14:15:18', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '0408e749-b5b6-4f7c-a163-324eff3e5e4e' User entered 'No (N)'	System	04 Aug 2020 19:15:29
	System	04 Aug 2020 19:15:29

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-04T14:15:20', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '0408e749-b5b6-4f7c-a163-324eff3e5e4e' User entered 'None (1)'	System	04 Aug 2020 19:15:29
	System	04 Aug 2020 19:15:29

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-04T14:15:27', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '0408e749-b5b6-4f7c-a163-324eff3e5e4e' User entered '04 Aug 2020 14:15'	System	04 Aug 2020 19:15:29
	System	04 Aug 2020 19:15:29

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered 'Day 3'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-05T17:56:59', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '3f245c4c-9a14-4f36-a987-5866364faa8f' User entered 'Does not interfere with activity (2)'	System	05 Aug 2020 22:57:13
	System	05 Aug 2020 22:57:13

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:33:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-05T17:57:01', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '3f245c4c-9a14-4f36-a987-5866364faa8f' User entered 'No (N)'	System	05 Aug 2020 22:57:13
	System	05 Aug 2020 22:57:13

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-05T17:57:03', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '3f245c4c-9a14-4f36-a987-5866364faa8f' User entered 'No (N)'	System	05 Aug 2020 22:57:13
	System	05 Aug 2020 22:57:13

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-05T17:57:06', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '3f245c4c-9a14-4f36-a987-5866364faa8f' User entered 'None (1)'	System	05 Aug 2020 22:57:13
	System	05 Aug 2020 22:57:13

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-05T17:57:09', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '3f245c4c-9a14-4f36-a987-5866364faa8f' User entered '05 Aug 2020 17:57'	System	05 Aug 2020 22:57:13
	System	05 Aug 2020 22:57:13

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered 'Day 4'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-06T14:13:47', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '1c4d64fa-a416-42a7-88e9-6b47c2917f24'	System	06 Aug 2020 19:14:00
User entered 'None (1)'	System	06 Aug 2020 19:14:00

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-06T14:13:50', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '1c4d64fa-a416-42a7-88e9-6b47c2917f24'	System	06 Aug 2020 19:14:00
User entered 'No (N)'	System	06 Aug 2020 19:14:00

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-06T14:13:53', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '1c4d64fa-a416-42a7-88e9-6b47c2917f24'	System	06 Aug 2020 19:14:00
User entered 'No (N)'	System	06 Aug 2020 19:14:00

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-06T14:13:56', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '1c4d64fa-a416-42a7-88e9-6b47c2917f24'	System	06 Aug 2020 19:14:00
User entered 'None (1)'	System	06 Aug 2020 19:14:00

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-06T14:13:58', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '1c4d64fa-a416-42a7-88e9-6b47c2917f24' User entered '06 Aug 2020 14:13'	System	06 Aug 2020 19:14:00
	System	06 Aug 2020 19:14:00

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered 'Day 5'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-07T18:03:56', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '013abe64-5008-466d-bf20-2b63dfcd3c8f' User entered 'None (1)'	System	07 Aug 2020 23:04:10
	System	07 Aug 2020 23:04:10

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:33:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-07T18:03:59', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '013abe64-5008-466d-bf20-2b63dfcd3c8f' User entered 'No (N)'	System	07 Aug 2020 23:04:10
	System	07 Aug 2020 23:04:10

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-07T18:04:02', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '013abe64-5008-466d-bf20-2b63dfcd3c8f' User entered 'No (N)'	System	07 Aug 2020 23:04:10
	System	07 Aug 2020 23:04:10

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-07T18:04:04', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '013abe64-5008-466d-bf20-2b63dfcd3c8f' User entered 'None (1)'	System	07 Aug 2020 23:04:10
	System	07 Aug 2020 23:04:10

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-07T18:04:07', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '013abe64-5008-466d-bf20-2b63dfcd3c8f' User entered '07 Aug 2020 18:04'	System	07 Aug 2020 23:04:10
	System	07 Aug 2020 23:04:10

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered 'Day 6'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-08T16:22:08', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'bdd874de-7d6a-4de4-ae99-16d3d993fa84' User entered 'None (1)'	System	08 Aug 2020 21:22:20
	System	08 Aug 2020 21:22:20

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:33:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-08T16:22:10', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'bdd874de-7d6a-4de4-ae99-16d3d993fa84' User entered 'No (N)'	System	08 Aug 2020 21:22:20
	System	08 Aug 2020 21:22:20

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-08T16:22:11', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'bdd874de-7d6a-4de4-ae99-16d3d993fa84' User entered 'No (N)'	System	08 Aug 2020 21:22:20
	System	08 Aug 2020 21:22:20

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-08T16:22:14', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'bdd874de-7d6a-4de4-ae99-16d3d993fa84' User entered 'None (1)'	System	08 Aug 2020 21:22:20
	System	08 Aug 2020 21:22:20

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-08T16:22:16', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'bdd874de-7d6a-4de4-ae99-16d3d993fa84' User entered '08 Aug 2020 16:22'	System	08 Aug 2020 21:22:20
	System	08 Aug 2020 21:22:20

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered 'Day 7'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-10T03:03:42', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'e1283df5-7e0b-40a2-b344-4a950246ffac'	System	10 Aug 2020 08:03:55
User entered 'None (1)'	System	10 Aug 2020 08:03:55

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:33:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-10T03:03:46', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'e1283df5-7e0b-40a2-b344-4a950246ffac'	System	10 Aug 2020 08:03:55
User entered 'No (N)'	System	10 Aug 2020 08:03:55

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-10T03:03:48', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'e1283df5-7e0b-40a2-b344-4a950246ffac'	System	10 Aug 2020 08:03:55
User entered 'No (N)'	System	10 Aug 2020 08:03:55

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-10T03:03:51', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'e1283df5-7e0b-40a2-b344-4a950246ffac'	System	10 Aug 2020 08:03:55
User entered 'None (1)'	System	10 Aug 2020 08:03:55

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-10T03:03:54', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'e1283df5-7e0b-40a2-b344-4a950246ffac' User entered '10 Aug 2020 03:03'	System	10 Aug 2020 08:03:55
	System	10 Aug 2020 08:03:55

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '03 Aug 2020 15:37'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '03 Aug 2020 18:07'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-03T19:37:06', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '14d6772a-fe6d-4433-bb0a-73fdfa4bd5f4' User entered 'None (0)'	System	04 Aug 2020 00:37:41
	System	04 Aug 2020 00:37:41

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-03T19:37:09', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '14d6772a-fe6d-4433-bb0a-73fdfa4bd5f4' User entered 'None (0)'	System	04 Aug 2020 00:37:41
	System	04 Aug 2020 00:37:41

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-03T19:37:18', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '14d6772a-fe6d-4433-bb0a-73fdfa4bd5f4' User entered 'None (0)'	System	04 Aug 2020 00:37:41
	System	04 Aug 2020 00:37:41

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-03T19:37:20', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '14d6772a-fe6d-4433-bb0a-73fdfa4bd5f4' User entered 'None (0)'	System	04 Aug 2020 00:37:41
	System	04 Aug 2020 00:37:41

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-03T19:37:24', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '14d6772a-fe6d-4433-bb0a-73fdfa4bd5f4' User entered 'None (0)'	System	04 Aug 2020 00:37:41
	System	04 Aug 2020 00:37:41

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-03T19:37:26', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '14d6772a-fe6d-4433-bb0a-73fdfa4bd5f4' User entered 'None (0)'	System	04 Aug 2020 00:37:41
	System	04 Aug 2020 00:37:41

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-03T19:37:35', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '14d6772a-fe6d-4433-bb0a-73fdfa4bd5f4'	System	04 Aug 2020 00:37:41
User entered 'No (N)'	System	04 Aug 2020 00:37:41

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-03T19:37:38', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '14d6772a-fe6d-4433-bb0a-73fdfa4bd5f4'	System	04 Aug 2020 00:37:41
User entered '03 Aug 2020 19:37'	System	04 Aug 2020 00:37:41

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '03 Aug 2020 19:02'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered 'Day 2'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-04T14:15:35', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'da33b59c-36ae-4aef-a9c1-b797cfce5d12' User entered 'None (0)'	System	04 Aug 2020 19:15:59
	System	04 Aug 2020 19:15:59

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-04T14:15:39', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'da33b59c-36ae-4aef-a9c1-b797cfce5d12' User entered 'None (0)'	System	04 Aug 2020 19:15:59
	System	04 Aug 2020 19:15:59

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-04T14:15:42', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'da33b59c-36ae-4aef-a9c1-b797cfce5d12' User entered 'None (0)'	System	04 Aug 2020 19:15:59
	System	04 Aug 2020 19:15:59

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-04T14:15:45', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'da33b59c-36ae-4aef-a9c1-b797cfce5d12' User entered 'None (0)'	System	04 Aug 2020 19:15:59
	System	04 Aug 2020 19:15:59

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-04T14:15:47', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'da33b59c-36ae-4aef-a9c1-b797cfce5d12' User entered 'None (0)'	System	04 Aug 2020 19:15:59
	System	04 Aug 2020 19:15:59

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-04T14:15:49', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'da33b59c-36ae-4aef-a9c1-b797cfce5d12' User entered 'None (0)'	System	04 Aug 2020 19:15:59
	System	04 Aug 2020 19:15:59

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-04T14:15:55', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'da33b59c-36ae-4aef-a9c1-b797cfce5d12'	System	04 Aug 2020 19:15:59
User entered 'No (N)'	System	04 Aug 2020 19:15:59

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-04T14:15:58', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'da33b59c-36ae-4aef-a9c1-b797cfce5d12'	System	04 Aug 2020 19:15:59
User entered '04 Aug 2020 14:15'	System	04 Aug 2020 19:15:59

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered 'Day 3'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-05T17:57:14', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'd12ca0a9-2dd6-4edd-8e34-51d3fb6b9576' User entered 'None (0)'	System	05 Aug 2020 22:57:37
	System	05 Aug 2020 22:57:37

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-05T17:57:17', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'd12ca0a9-2dd6-4edd-8e34-51d3fb6b9576' User entered 'None (0)'	System	05 Aug 2020 22:57:37
	System	05 Aug 2020 22:57:37

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-05T17:57:19', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'd12ca0a9-2dd6-4edd-8e34-51d3fb6b9576' User entered 'None (0)'	System	05 Aug 2020 22:57:37
	System	05 Aug 2020 22:57:37

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-05T17:57:21', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'd12ca0a9-2dd6-4edd-8e34-51d3fb6b9576' User entered 'None (0)'	System	05 Aug 2020 22:57:37
	System	05 Aug 2020 22:57:37

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-05T17:57:23', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'd12ca0a9-2dd6-4edd-8e34-51d3fb6b9576' User entered 'None (0)'	System	05 Aug 2020 22:57:37
	System	05 Aug 2020 22:57:37

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-05T17:57:25', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'd12ca0a9-2dd6-4edd-8e34-51d3fb6b9576' User entered 'None (0)'	System	05 Aug 2020 22:57:37
	System	05 Aug 2020 22:57:37

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-05T17:57:32', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'd12ca0a9-2dd6-4edd-8e34-51d3fb6b9576' User entered 'No (N)'	System	05 Aug 2020 22:57:37
	System	05 Aug 2020 22:57:37

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-05T17:57:36', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'd12ca0a9-2dd6-4edd-8e34-51d3fb6b9576' User entered '05 Aug 2020 17:57'	System	05 Aug 2020 22:57:37
	System	05 Aug 2020 22:57:37

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered 'Day 4'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-06T14:14:03', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'bd80d404-6f35-49ff-8523-19c7c2071842'	System	06 Aug 2020 19:14:28
User entered 'None (0)'	System	06 Aug 2020 19:14:28

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-06T14:14:05', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'bd80d404-6f35-49ff-8523-19c7c2071842'	System	06 Aug 2020 19:14:28
User entered 'None (0)'	System	06 Aug 2020 19:14:28

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-06T14:14:08', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'bd80d404-6f35-49ff-8523-19c7c2071842' User entered 'None (0)'	System	06 Aug 2020 19:14:28
	System	06 Aug 2020 19:14:28

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-06T14:14:10', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'bd80d404-6f35-49ff-8523-19c7c2071842' User entered 'None (0)'	System	06 Aug 2020 19:14:28
	System	06 Aug 2020 19:14:28

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-06T14:14:13', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'bd80d404-6f35-49ff-8523-19c7c2071842' User entered 'None (0)'	System	06 Aug 2020 19:14:28
	System	06 Aug 2020 19:14:28

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-06T14:14:16', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'bd80d404-6f35-49ff-8523-19c7c2071842'	System	06 Aug 2020 19:14:28
User entered 'None (0)'	System	06 Aug 2020 19:14:28

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-06T14:14:21', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'bd80d404-6f35-49ff-8523-19c7c2071842'	System	06 Aug 2020 19:14:28
User entered 'No (N)'	System	06 Aug 2020 19:14:28

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-06T14:14:26', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'bd80d404-6f35-49ff-8523-19c7c2071842'	System	06 Aug 2020 19:14:28
User entered '06 Aug 2020 14:14'	System	06 Aug 2020 19:14:28

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered 'Day 5'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-07T18:04:11', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '2bbb0884-bf55-4764-9236-7045d4cb7f42'	System	07 Aug 2020 23:04:28
User entered 'None (0)'	System	07 Aug 2020 23:04:28

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-07T18:04:14', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '2bbb0884-bf55-4764-9236-7045d4cb7f42' User entered 'None (0)'	System	07 Aug 2020 23:04:28
	System	07 Aug 2020 23:04:28

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-07T18:04:16', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '2bbb0884-bf55-4764-9236-7045d4cb7f42' User entered 'None (0)'	System	07 Aug 2020 23:04:28
	System	07 Aug 2020 23:04:28

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-07T18:04:18', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '2bbb0884-bf55-4764-9236-7045d4cb7f42' User entered 'None (0)'	System	07 Aug 2020 23:04:28
	System	07 Aug 2020 23:04:28

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-07T18:04:20', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '2bbb0884-bf55-4764-9236-7045d4cb7f42' User entered 'None (0)'	System	07 Aug 2020 23:04:28
	System	07 Aug 2020 23:04:28

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-07T18:04:22', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '2bbb0884-bf55-4764-9236-7045d4cb7f42' User entered 'None (0)'	System	07 Aug 2020 23:04:28
	System	07 Aug 2020 23:04:28

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-07T18:04:25', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '2bbb0884-bf55-4764-9236-7045d4cb7f42'	System	07 Aug 2020 23:04:28
User entered 'No (N)'	System	07 Aug 2020 23:04:28

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-07T18:04:27', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '2bbb0884-bf55-4764-9236-7045d4cb7f42'	System	07 Aug 2020 23:04:28
User entered '07 Aug 2020 18:04'	System	07 Aug 2020 23:04:28

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered 'Day 6'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-08T16:22:19', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'ccfe4354-5216-40f1-a636-b3595682b18f' User entered 'None (0)'	System	08 Aug 2020 21:22:36
	System	08 Aug 2020 21:22:36

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-08T16:22:22', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'ccfe4354-5216-40f1-a636-b3595682b18f' User entered 'None (0)'	System	08 Aug 2020 21:22:36
	System	08 Aug 2020 21:22:36

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-08T16:22:24', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'ccfe4354-5216-40f1-a636-b3595682b18f' User entered 'None (0)'	System	08 Aug 2020 21:22:36
	System	08 Aug 2020 21:22:36

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-08T16:22:26', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'ccfe4354-5216-40f1-a636-b3595682b18f' User entered 'None (0)'	System	08 Aug 2020 21:22:36
	System	08 Aug 2020 21:22:36

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-08T16:22:27', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'ccfe4354-5216-40f1-a636-b3595682b18f' User entered 'None (0)'	System	08 Aug 2020 21:22:36
	System	08 Aug 2020 21:22:36

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-08T16:22:29', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'ccfe4354-5216-40f1-a636-b3595682b18f' User entered 'None (0)'	System	08 Aug 2020 21:22:36
	System	08 Aug 2020 21:22:36

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-08T16:22:32', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'ccfe4354-5216-40f1-a636-b3595682b18f' User entered 'No (N)'	System	08 Aug 2020 21:22:36
	System	08 Aug 2020 21:22:36

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-08T16:22:34', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'ccfe4354-5216-40f1-a636-b3595682b18f' User entered '08 Aug 2020 16:22'	System	08 Aug 2020 21:22:36
	System	08 Aug 2020 21:22:36

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered 'Day 7'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-10T03:03:58', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'be7649ba-e951-4e4c-8fcb-27c2662049c4' User entered 'None (0)'	System	10 Aug 2020 08:04:17
	System	10 Aug 2020 08:04:17

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-10T03:04:00', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'be7649ba-e951-4e4c-8fcb-27c2662049c4' User entered 'None (0)'	System	10 Aug 2020 08:04:17
	System	10 Aug 2020 08:04:17

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-10T03:04:02', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'be7649ba-e951-4e4c-8fcb-27c2662049c4' User entered 'None (0)'	System	10 Aug 2020 08:04:17
	System	10 Aug 2020 08:04:17

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-10T03:04:04', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'be7649ba-e951-4e4c-8fcb-27c2662049c4' User entered 'None (0)'	System	10 Aug 2020 08:04:17
	System	10 Aug 2020 08:04:17

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-10T03:04:06', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'be7649ba-e951-4e4c-8fcb-27c2662049c4' User entered 'None (0)'	System	10 Aug 2020 08:04:17
	System	10 Aug 2020 08:04:17

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-10T03:04:08', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'be7649ba-e951-4e4c-8fcb-27c2662049c4' User entered 'None (0)'	System	10 Aug 2020 08:04:17
	System	10 Aug 2020 08:04:17

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-10T03:04:11', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'be7649ba-e951-4e4c-8fcb-27c2662049c4' User entered 'No (N)'	System	10 Aug 2020 08:04:17
	System	10 Aug 2020 08:04:17

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-08-10T03:04:14', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'be7649ba-e951-4e4c-8fcb-27c2662049c4' User entered '10 Aug 2020 03:04'	System	10 Aug 2020 08:04:17
	System	10 Aug 2020 08:04:17

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 20:37:02

US3362023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 20:37:02

US3362023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	10 Aug 2020 18:39:06

US3362023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered '10 Aug 2020'	Crystal Rowell (b) (4)	10 Aug 2020 18:39:06

US3362023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Contact Made (CONTACT MADE)'	Crystal Rowell (b) (4)	10 Aug 2020 18:39:06

US3362023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered empty.	Crystal Rowell (b) (4)	10 Aug 2020 18:39:06

US3362023

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 22:30:02
User entered 'No (N)'	Crystal Rowell (b) (4)	10 Aug 2020 18:39:14

US3362023

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered 'l'	System	24 Aug 2020 22:30:02
User entered empty.	System	10 Aug 2020 18:39:14

US3362023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 22:30:28

US3362023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered '17 Aug 2020'	(b) (4), (b) (6)	24 Aug 2020 22:30:28

US3362023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 22:30:28

US3362023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 22:30:28

US3362023

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 22:30:37

US3362023

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered 'I'	System	24 Aug 2020 22:30:37

US3362023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 22:30:45

US3362023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	14 Dec 2020 19:38:51
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	14 Dec 2020 19:24:21
User entered '24 Aug 2020'	(b) (4), (b) (6)	24 Aug 2020 22:30:45

US3362023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	24 Aug 2020 22:30:45

US3362023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 22:30:45

US3362023

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 22:30:52

US3362023

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered 'I'	System	24 Aug 2020 22:30:52

US3362023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:33:17

US3362023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User closed query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	(b) (4)	14 Dec 2020 19:38:51
User opened query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	14 Dec 2020 19:24:21
User entered '31 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 20:33:17

US3362023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[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 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	31 Aug 2020 20:33:17

US3362023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered 'VISIT2'	System	31 Aug 2020 20:33:17

US3362023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	31 Aug 2020 20:34:06

US3362023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:34:06

US3362023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
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).	(b) (4) System	14 Dec 2020 19:38:51
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	14 Dec 2020 19:24:21
User entered '31 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 20:34:06

US3362023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered '12:31'	(b) (4), (b) (6)	31 Aug 2020 20:34:06

US3362023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered '31 Aug 2020 12:31'	System	31 Aug 2020 20:34:06

US3362023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered '36.9' C	(b) (4), (b) (6)	31 Aug 2020 20:34:06

US3362023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Oral (Oral)'	(b) (4), (b) (6)	31 Aug 2020 20:34:06

US3362023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:34:06

US3362023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered '80'	(b) (4), (b) (6)	31 Aug 2020 20:34:06

US3362023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered 'bpm'	System	31 Aug 2020 20:34:06

US3362023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered '14'	(b) (4), (b) (6)	31 Aug 2020 20:34:06

US3362023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered 'breaths/min'	System	31 Aug 2020 20:34:06

US3362023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered '145'	(b) (4), (b) (6)	31 Aug 2020 20:34:06

US3362023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered 'mmHg'	System	31 Aug 2020 20:34:06

US3362023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered '89'	(b) (4), (b) (6)	31 Aug 2020 20:34:06

US3362023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered 'mmHg'	System	31 Aug 2020 20:34:06

US3362023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	31 Aug 2020 20:34:06

US3362023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	31 Aug 2020 20:34:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 20:34:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 20:34:10
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:34:06
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:34:06

US3362023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:34:06

US3362023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:34:06

US3362023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered empty.	System	31 Aug 2020 20:34:06

US3362023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:34:06

US3362023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:34:06

US3362023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:34:06

US3362023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:34:06

US3362023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered empty.	System	31 Aug 2020 20:34:06

US3362023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:34:06

US3362023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered empty.	System	31 Aug 2020 20:34:06

US3362023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:34:06

US3362023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered empty.	System	31 Aug 2020 20:34:06

US3362023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:34:06

US3362023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered empty.	System	31 Aug 2020 20:34:06

US3362023

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:34:22

US3362023

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User closed query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	(b) (4)	14 Dec 2020 19:38:51
User opened query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).		14 Dec 2020 19:24:21
User entered '31 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 20:34:22

US3362023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:37:20

US3362023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User closed query 'Per CDM: Response noted however, please clarify and confirm the supporting AE #number, if not entered already, please consider updating the AE eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:55:54
Comment added 'AE #1'.	Amy Thomassie (b) (4)	07 Sep 2020 16:34:31
Query 'Per CDM: Response noted however, please clarify and confirm the supporting AE #number, if not entered already, please consider updating the AE eCRF.' answered with 'AE #1. ' (Site from DM).	(b) (4) Amy Thomassie (b) (4)	07 Sep 2020 16:34:10
User opened query 'Per CDM: Response noted however, please clarify and confirm the supporting AE #number, if not entered already, please consider updating the AE eCRF.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 09:43:47
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	(b) (4), (b) (6)	31 Aug 2020 20:37:20

US3362023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

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 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Patient reported strange taste in mouth, numbness and mild swelling of the tongue with onset 1 hour post injection. Symptoms lasted 2 hours and resolved completely without medication or intervention.'	(b) (4), (b) (6)	31 Aug 2020 20:37:20

US3362023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered empty.	System	31 Aug 2020 20:37:20

US3362023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:37:20

US3362023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:37:20

US3362023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered empty.	System	31 Aug 2020 20:37:20

US3362023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:37:20

US3362023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered empty.	System	31 Aug 2020 20:37:20

US3362023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered empty.	System	31 Aug 2020 20:37:20

US3362023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:37:57

US3362023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User closed query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	(b) (4)	14 Dec 2020 19:38:51
User opened query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	14 Dec 2020 19:24:21
User entered '31 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 20:37:57

US3362023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered '12:44'	(b) (4), (b) (6)	31 Aug 2020 20:37:57

US3362023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered '31 Aug 2020 12:44'	System	31 Aug 2020 20:37:57

US3362023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:33:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
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).	(b) (4) System	14 Dec 2020 19:38:51
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	14 Dec 2020 19:24:21
User entered '31 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 20:38:17

US3362023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:33:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	31 Aug 2020 20:38:17

US3362023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:33:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:38:17

US3362023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:33:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered '12:46'	(b) (4), (b) (6)	31 Aug 2020 20:38:17

US3362023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered '31 Aug 2020 12:46'	System	31 Aug 2020 20:38:17

US3362023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:33:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	31 Aug 2020 20:38:17

US3362023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:33:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:38:17

US3362023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:38:17

US3362023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered empty.	System	31 Aug 2020 20:38:17

US3362023

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:38:22

US3362023

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered 'I'	System	31 Aug 2020 20:38:22

US3362023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 15:41:50

US3362023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	14 Dec 2020 19:38:51
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	14 Dec 2020 19:24:21
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 15:41:50

US3362023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:41:50

US3362023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:41:50

US3362023

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:41:54

US3362023

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered 'I'	System	10 Sep 2020 15:41:54

US3362023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 21:55:56

US3362023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	14 Dec 2020 19:38:51
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	14 Dec 2020 19:24:21
User entered '15 Sep 2020'	(b) (4), (b) (6)	15 Sep 2020 21:55:56

US3362023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	15 Sep 2020 21:55:56

US3362023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 21:55:56

US3362023

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 21:55:45

US3362023

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered 'I'	System	15 Sep 2020 21:55:45

US3362023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 20:32:17

US3362023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	14 Dec 2020 19:38:51
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	14 Dec 2020 19:24:21
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 20:32:17

US3362023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 20:32:17

US3362023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 20:32:17

US3362023

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 20:32:32

US3362023

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered 'I'	System	22 Sep 2020 20:32:32

US3362023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:02:52

US3362023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User closed query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	(b) (4)	14 Dec 2020 19:38:51
User opened query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	14 Dec 2020 19:24:21
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 19:02:52

US3362023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[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 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:02:52

US3362023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered 'VISIT3'	System	28 Sep 2020 19:02:52

US3362023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:03:37

US3362023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
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).	(b) (4) System	14 Dec 2020 19:38:51
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	14 Dec 2020 19:24:21
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 19:03:37

US3362023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered '11:35'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:03:37

US3362023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered '28 Sep 2020 11:35'	System	28 Sep 2020 19:03:37

US3362023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered '37.3' C	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:03:37

US3362023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:03:37

US3362023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:03:37

US3362023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User closed query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	28 Sep 2020 19:03:49
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	28 Sep 2020 19:03:49
User entered '90' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 19:03:49
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	28 Sep 2020 19:03:37
User entered '18'	(b) (4), (b) (6)	28 Sep 2020 19:03:37

US3362023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered 'bpm'	System	28 Sep 2020 19:03:37

US3362023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User closed query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	28 Sep 2020 19:03:49
Query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	28 Sep 2020 19:03:49
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 19:03:49
User opened query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	28 Sep 2020 19:03:37
User entered '90'	(b) (4), (b) (6)	28 Sep 2020 19:03:37

US3362023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered 'breaths/min'	System	28 Sep 2020 19:03:37

US3362023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered '119'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:03:37

US3362023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered 'mmHg'	System	28 Sep 2020 19:03:37

US3362023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered '79'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:03:37

US3362023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered 'mmHg'	System	28 Sep 2020 19:03:37

US3362023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16

US3362023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16

US3362023

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:03:56

US3362023

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User closed query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	(b) (4)	14 Dec 2020 19:38:51
User opened query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).		14 Dec 2020 19:24:21
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 19:03:56

US3362023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:04:16

US3362023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User closed query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	(b) (4)	14 Dec 2020 19:38:51
User opened query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	14 Dec 2020 19:24:21
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 19:04:16

US3362023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered '11:41'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:04:16

US3362023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered '28 Sep 2020 11:41'	System	28 Sep 2020 19:04:16

US3362023

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	15 Feb 2021 17:41:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:04:20

US3362023

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered 'I'	System	28 Sep 2020 19:04:20

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered 'Day 64'	System	03 Aug 2020 20:37:02

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-10-03T07:05:23', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '5eedb7bd-735e-421a-96cc-6d25be6882ba' User entered 'No (N)'	System	03 Oct 2020 12:05:55
	System	03 Oct 2020 12:05:55

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-10-03T07:05:29', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '5eedb7bd-735e-421a-96cc-6d25be6882ba' User entered 'No (N)'	System	03 Oct 2020 12:05:55
	System	03 Oct 2020 12:05:55

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-10-03T07:05:51', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '5eedb7bd-735e-421a-96cc-6d25be6882ba' User entered '03 Oct 2020 07:05:51'	System	03 Oct 2020 12:05:55
	System	03 Oct 2020 12:05:55

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered '03 Oct 2020 00:01'	System	03 Aug 2020 20:37:02

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered '07 Oct 2020 23:59'	System	03 Aug 2020 20:37:02

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered 'Day 71'	System	03 Aug 2020 20:37:02

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-10-10T07:00:43', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'b957da9b-b2ed-49f3-87e5-4f367b2e789b'	System	10 Oct 2020 12:01:05
User entered 'No (N)'	System	10 Oct 2020 12:01:05

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-10-10T07:00:51', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'b957da9b-b2ed-49f3-87e5-4f367b2e789b'	System	10 Oct 2020 12:01:05
User entered 'No (N)'	System	10 Oct 2020 12:01:05

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-10-10T07:00:59', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'b957da9b-b2ed-49f3-87e5-4f367b2e789b' User entered '10 Oct 2020 07:00:59'	System	10 Oct 2020 12:01:05
	System	10 Oct 2020 12:01:05

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered '10 Oct 2020 00:01'	System	03 Aug 2020 20:37:02

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered '14 Oct 2020 23:59'	System	03 Aug 2020 20:37:02

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered 'Day 78'	System	03 Aug 2020 20:37:02

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-10-17T05:43:40', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '5afa2d7d-72fa-4c72-815e-233b7cf71687'	System	17 Oct 2020 10:43:51
User entered 'No (N)'	System	17 Oct 2020 10:43:51

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-10-17T05:43:44', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '5afa2d7d-72fa-4c72-815e-233b7cf71687'	System	17 Oct 2020 10:43:51
User entered 'No (N)'	System	17 Oct 2020 10:43:51

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-10-17T05:43:46', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '5afa2d7d-72fa-4c72-815e-233b7cf71687' User entered '17 Oct 2020 05:43:46'	System	17 Oct 2020 10:43:51
	System	17 Oct 2020 10:43:51

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered '17 Oct 2020 00:01'	System	03 Aug 2020 20:37:02

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered '21 Oct 2020 23:59'	System	03 Aug 2020 20:37:02

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered 'Day 92'	System	03 Aug 2020 20:37:02

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-10-31T05:43:05', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '60a23468-64fe-4c9d-bd3a-8ed3c630eff3'	System	31 Oct 2020 10:43:22
User entered 'No (N)'	System	31 Oct 2020 10:43:22

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-10-31T05:43:10', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '60a23468-64fe-4c9d-bd3a-8ed3c630eff3'	System	31 Oct 2020 10:43:22
User entered 'No (N)'	System	31 Oct 2020 10:43:22

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-10-31T05:43:19', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '60a23468-64fe-4c9d-bd3a-8ed3c630eff3' User entered '31 Oct 2020 05:43:19'	System	31 Oct 2020 10:43:22
	System	31 Oct 2020 10:43:22

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered '31 Oct 2020 00:01'	System	03 Aug 2020 20:37:02

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered '04 Nov 2020 23:59'	System	03 Aug 2020 20:37:02

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered 'Day 99'	System	03 Aug 2020 20:37:02

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-11-07T05:41:11', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'c21c9a71-a99a-4bb9-b14f-f0e232c87291' User entered 'No (N)'	System	07 Nov 2020 11:41:32
	System	07 Nov 2020 11:41:32

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-11-07T05:41:18', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'c21c9a71-a99a-4bb9-b14f-f0e232c87291'	System	07 Nov 2020 11:41:32
User entered 'No (N)'	System	07 Nov 2020 11:41:32

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-11-07T05:41:29', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'c21c9a71-a99a-4bb9-b14f-f0e232c87291' User entered '07 Nov 2020 05:41:29'	System	07 Nov 2020 11:41:32
	System	07 Nov 2020 11:41:32

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered '07 Nov 2020 00:01'	System	03 Aug 2020 20:37:02

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered '11 Nov 2020 23:59'	System	03 Aug 2020 20:37:02

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered 'Day 106'	System	03 Aug 2020 20:37:02

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-11-14T06:02:58', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '59498be5-fc54-42a2-b21b-284312b90f72'	System	14 Nov 2020 12:03:08
User entered 'No (N)'	System	14 Nov 2020 12:03:08

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-11-14T06:03:01', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '59498be5-fc54-42a2-b21b-284312b90f72'	System	14 Nov 2020 12:03:08
User entered 'No (N)'	System	14 Nov 2020 12:03:08

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-11-14T06:03:03', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '59498be5-fc54-42a2-b21b-284312b90f72' User entered '14 Nov 2020 06:03:03'	System	14 Nov 2020 12:03:08
	System	14 Nov 2020 12:03:08

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered '14 Nov 2020 00:01'	System	03 Aug 2020 20:37:02

US3362023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:05:45
Data entry locked.	System	03 Aug 2020 20:37:02
User entered '18 Nov 2020 23:59'	System	03 Aug 2020 20:37:02

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-11-20T12:03:19', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '065d881c-9abb-4375-885e-fd7302af8ad2'	System	20 Nov 2020 18:04:28
User entered 'Yes (Y)'	System	20 Nov 2020 18:04:28

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-11-20T12:03:30', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '065d881c-9abb-4375-885e-fd7302af8ad2'	System	20 Nov 2020 18:04:28
User entered 'Yes (Y)'	System	20 Nov 2020 18:04:28

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-11-20T12:03:37', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '065d881c-9abb-4375-885e-fd7302af8ad2'	System	20 Nov 2020 18:04:28
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Nov 2020 18:04:28

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-11-20T12:03:50', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '065d881c-9abb-4375-885e-fd7302af8ad2'	System	20 Nov 2020 18:04:28
User entered 'No (N)'	System	20 Nov 2020 18:04:28

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-11-20T12:03:56', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '065d881c-9abb-4375-885e-fd7302af8ad2'	System	20 Nov 2020 18:04:28
User entered 'No (N)'	System	20 Nov 2020 18:04:28

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-11-20T12:04:17', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '065d881c-9abb-4375-885e-fd7302af8ad2' User entered '20 Nov 2020 12:04:17'	System	20 Nov 2020 18:04:28
	System	20 Nov 2020 18:04:28

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-11-25T06:07:58', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '3d0ca39c-8360-42ee-a45d-1113e1037bbf' User entered 'No (N)'	System	25 Nov 2020 12:08:12
	System	25 Nov 2020 12:08:12

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-11-25T06:08:03', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '3d0ca39c-8360-42ee-a45d-1113e1037bbf' User entered 'No (N)'	System	25 Nov 2020 12:08:12

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-11-25T06:08:06', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '3d0ca39c-8360-42ee-a45d-1113e1037bbf' User entered '25 Nov 2020 06:08:06'	System	25 Nov 2020 12:08:12
	System	25 Nov 2020 12:08:12

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-12-02T04:23:37', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '03d48087-1909-4b5b-8fe5-7e415a8de2e5'	System	02 Dec 2020 10:23:49
User entered 'No (N)'	System	02 Dec 2020 10:23:49

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with known SARS-CoV-2 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-12-02T04:23:43', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '03d48087-1909-4b5b-8fe5-7e415a8de2e5'	System	02 Dec 2020 10:23:49
User entered 'No (N)'	System	02 Dec 2020 10:23:49

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-12-02T04:23:46', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '03d48087-1909-4b5b-8fe5-7e415a8de2e5' User entered '02 Dec 2020 04:23:46'	System	02 Dec 2020 10:23:49
	System	02 Dec 2020 10:23:49

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-12-09T06:48:34', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '65761382-4613-4919-bde6-e7f8f04c6f28'	System	09 Dec 2020 12:48:44
User entered 'No (N)'	System	09 Dec 2020 12:48:44

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-12-09T06:48:37', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '65761382-4613-4919-bde6-e7f8f04c6f28'	System	09 Dec 2020 12:48:44
User entered 'No (N)'	System	09 Dec 2020 12:48:44

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-12-09T06:48:40', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '65761382-4613-4919-bde6-e7f8f04c6f28' User entered '09 Dec 2020 06:48:40'	System	09 Dec 2020 12:48:44
	System	09 Dec 2020 12:48:44

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-12-16T06:54:30', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '301d04db-5b36-4f70-924d-b2f75e21dc41'	System	16 Dec 2020 12:54:44
User entered 'No (N)'	System	16 Dec 2020 12:54:44
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-12-16T06:54:35', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '301d04db-5b36-4f70-924d-b2f75e21dc41'	System	16 Dec 2020 12:54:44
User entered 'No (N)'	System	16 Dec 2020 12:54:44
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-12-16T06:54:38', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '301d04db-5b36-4f70-924d-b2f75e21dc41'	System	16 Dec 2020 12:54:44
User entered '16 Dec 2020 06:54:38'	System	16 Dec 2020 12:54:44
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-12-23T20:04:43', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'f195bed1-7e15-4edc-91ac-4d0895d0accd'	System	24 Dec 2020 02:05:03
User entered 'No (N)'	System	24 Dec 2020 02:05:03
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with known SARS-CoV-2 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-12-23T20:04:56', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'f195bed1-7e15-4edc-91ac-4d0895d0accd'	System	24 Dec 2020 02:05:03
User entered 'No (N)'	System	24 Dec 2020 02:05:03
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-12-23T20:05:00', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'f195bed1-7e15-4edc-91ac-4d0895d0accd'	System	24 Dec 2020 02:05:03
User entered '23 Dec 2020 20:05:00'	System	24 Dec 2020 02:05:03
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-12-30T06:00:56', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'a25b9bfb-57f6-47cd-bb3e-6501f8c78fd2'	System	30 Dec 2020 12:01:10
User entered 'No (N)'	System	30 Dec 2020 12:01:10
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-12-30T06:00:59', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'a25b9bfb-57f6-47cd-bb3e-6501f8c78fd2'	System	30 Dec 2020 12:01:10
User entered 'No (N)'	System	30 Dec 2020 12:01:10
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2020-12-30T06:01:03', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'a25b9bfb-57f6-47cd-bb3e-6501f8c78fd2'	System	30 Dec 2020 12:01:10
User entered '30 Dec 2020 06:01:03'	System	30 Dec 2020 12:01:10
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-01-06T17:05:53', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'd7a97519-9bd2-4994-b45c-d471f36e4d42'	System	06 Jan 2021 23:06:07
User entered 'No (N)'	System	06 Jan 2021 23:06:07
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-01-06T17:05:58', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'd7a97519-9bd2-4994-b45c-d471f36e4d42'	System	06 Jan 2021 23:06:07
User entered 'No (N)'	System	06 Jan 2021 23:06:07
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-01-06T17:06:01', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'd7a97519-9bd2-4994-b45c-d471f36e4d42'	System	06 Jan 2021 23:06:07
User entered '06 Jan 2021 17:06:01'	System	06 Jan 2021 23:06:07
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-01-13T06:28:01', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'cd8f23d7-7f4a-45d8-9d49-337a26b72156'	System	13 Jan 2021 12:28:43
User entered 'No (N)'	System	13 Jan 2021 12:28:43
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with known SARS-CoV-2 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-01-13T06:28:07', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'cd8f23d7-7f4a-45d8-9d49-337a26b72156'	System	13 Jan 2021 12:28:43
User entered 'Yes (Y)'	System	13 Jan 2021 12:28:43
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-01-13T06:28:26', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'cd8f23d7-7f4a-45d8-9d49-337a26b72156'	System	13 Jan 2021 12:28:43
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Jan 2021 12:28:43
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

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Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-01-13T06:28:33', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'cd8f23d7-7f4a-45d8-9d49-337a26b72156'	System	13 Jan 2021 12:28:43
User entered '13 Jan 2021 06:28:33'	System	13 Jan 2021 12:28:43
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-01-20T06:39:10', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'f5f0a846-82ab-4ae9-96e9-a66cc55a5e6e'	System	20 Jan 2021 12:39:18
User entered 'No (N)'	System	20 Jan 2021 12:39:18
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-01-20T06:39:13', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'f5f0a846-82ab-4ae9-96e9-a66cc55a5e6e'	System	20 Jan 2021 12:39:18
User entered 'No (N)'	System	20 Jan 2021 12:39:18
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-01-20T06:39:16', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'f5f0a846-82ab-4ae9-96e9-a66cc55a5e6e'	System	20 Jan 2021 12:39:18
User entered '20 Jan 2021 06:39:16'	System	20 Jan 2021 12:39:18
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 11:58:00

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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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-01-27T06:35:33', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'a03905ee-ca61-483f-a740-22499b7fc1b6'	System	27 Jan 2021 12:35:43
User entered 'No (N)'	System	27 Jan 2021 12:35:43
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with known SARS-CoV-2 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-01-27T06:35:37', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'a03905ee-ca61-483f-a740-22499b7fc1b6'	System	27 Jan 2021 12:35:43
User entered 'No (N)'	System	27 Jan 2021 12:35:43
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-01-27T06:35:40', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'a03905ee-ca61-483f-a740-22499b7fc1b6'	System	27 Jan 2021 12:35:43
User entered '27 Jan 2021 06:35:40'	System	27 Jan 2021 12:35:43
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-02-03T06:25:52', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'b333982a-8f25-4010-aa71-94e39f965eb0'	System	03 Feb 2021 12:26:04
User entered 'No (N)'	System	03 Feb 2021 12:26:04
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-02-03T06:25:55', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'b333982a-8f25-4010-aa71-94e39f965eb0'	System	03 Feb 2021 12:26:04
User entered 'No (N)'	System	03 Feb 2021 12:26:04
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-02-03T06:25:59', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'b333982a-8f25-4010-aa71-94e39f965eb0'	System	03 Feb 2021 12:26:04
User entered '03 Feb 2021 06:25:59'	System	03 Feb 2021 12:26:04
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 11:58:00

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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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-02-10T06:37:59', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '93adf5ed-258a-451e-a0c0-f5d792e5e8ba'	System	10 Feb 2021 12:38:10
User entered 'No (N)'	System	10 Feb 2021 12:38:10
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-02-10T06:38:03', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '93adf5ed-258a-451e-a0c0-f5d792e5e8ba'	System	10 Feb 2021 12:38:10
User entered 'No (N)'	System	10 Feb 2021 12:38:10
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-02-10T06:38:06', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '93adf5ed-258a-451e-a0c0-f5d792e5e8ba'	System	10 Feb 2021 12:38:10
User entered '10 Feb 2021 06:38:06'	System	10 Feb 2021 12:38:10
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

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Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-02-17T06:55:23', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '1e6d6672-64bd-4236-b871-c060eeb6766d'	System	17 Feb 2021 12:55:32
User entered 'No (N)'	System	17 Feb 2021 12:55:32
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-02-17T06:55:26', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '1e6d6672-64bd-4236-b871-c060eeb6766d'	System	17 Feb 2021 12:55:32
User entered 'No (N)'	System	17 Feb 2021 12:55:32
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-02-17T06:55:29', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '1e6d6672-64bd-4236-b871-c060eeb6766d'	System	17 Feb 2021 12:55:32
User entered '17 Feb 2021 06:55:29'	System	17 Feb 2021 12:55:32
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-02-26T06:08:11-06:00', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '11369c9a-7a96-4a36-9654-fe14e0c7db8a'	System	26 Feb 2021 12:08:21
User entered 'No (N)'	System	26 Feb 2021 12:08:21
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with known SARS-CoV-2 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-02-26T06:08:15-06:00', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '11369c9a-7a96-4a36-9654-fe14e0c7db8a'	System	26 Feb 2021 12:08:21
User entered 'No (N)'	System	26 Feb 2021 12:08:21
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-02-26T06:08:18-06:00', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '11369c9a-7a96-4a36-9654-fe14e0c7db8a'	System	26 Feb 2021 12:08:21
User entered '26 Feb 2021 12:08:18'	System	26 Feb 2021 12:08:21
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-03-03T00:19:58-06:00', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'c5fbf933-9e66-428f-b790-831a37effec4'	System	03 Mar 2021 06:20:08
User entered 'No (N)'	System	03 Mar 2021 06:20:08
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-03-03T00:20:02-06:00', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'c5fbf933-9e66-428f-b790-831a37effec4'	System	03 Mar 2021 06:20:08
User entered 'No (N)'	System	03 Mar 2021 06:20:08
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-03-03T00:20:05-06:00', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'c5fbf933-9e66-428f-b790-831a37effec4'	System	03 Mar 2021 06:20:08
User entered '03 Mar 2021 06:20:05'	System	03 Mar 2021 06:20:08
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-03-10T02:15:59-06:00', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '5a0531cf-dc4d-4262-8821-a894bcf04c5b'	System	10 Mar 2021 08:16:10
User entered 'No (N)'	System	10 Mar 2021 08:16:10
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-03-10T02:16:04-06:00', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '5a0531cf-dc4d-4262-8821-a894bcf04c5b'	System	10 Mar 2021 08:16:10
User entered 'No (N)'	System	10 Mar 2021 08:16:10
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-03-10T02:16:07-06:00', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '5a0531cf-dc4d-4262-8821-a894bcf04c5b'	System	10 Mar 2021 08:16:10
User entered '10 Mar 2021 02:16:07'	System	10 Mar 2021 08:16:10
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-03-17T00:40:47-05:00', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '183056f8-4bc8-443d-b498-75b0aa4d6350'	System	17 Mar 2021 05:40:58
User entered 'No (N)'	System	17 Mar 2021 05:40:58
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-03-17T00:40:50-05:00', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '183056f8-4bc8-443d-b498-75b0aa4d6350'	System	17 Mar 2021 05:40:58
User entered 'No (N)'	System	17 Mar 2021 05:40:58
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-03-17T00:40:52-05:00', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '183056f8-4bc8-443d-b498-75b0aa4d6350'	System	17 Mar 2021 05:40:58
User entered '17 Mar 2021 00:40:52'	System	17 Mar 2021 05:40:58
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-03-24T06:26:50-05:00', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '1dae942c-f115-4cf3-a5ea-2ac0aabfd7aa'	System	24 Mar 2021 11:26:58
User entered 'No (N)'	System	24 Mar 2021 11:26:58
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-03-24T06:26:53-05:00', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '1dae942c-f115-4cf3-a5ea-2ac0aabfd7aa'	System	24 Mar 2021 11:26:58
User entered 'No (N)'	System	24 Mar 2021 11:26:58
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-03-24T06:26:55-05:00', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '1dae942c-f115-4cf3-a5ea-2ac0aabfd7aa'	System	24 Mar 2021 11:26:58
User entered '24 Mar 2021 06:26:55'	System	24 Mar 2021 11:26:58
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-03-31T06:00:37-05:00', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'e3876ddd-e10f-4d64-97a0-553b61cdf856'	System	31 Mar 2021 11:00:48
User entered 'No (N)'	System	31 Mar 2021 11:00:48
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-03-31T06:00:40-05:00', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'e3876ddd-e10f-4d64-97a0-553b61cdf856'	System	31 Mar 2021 11:00:48
User entered 'No (N)'	System	31 Mar 2021 11:00:48
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-03-31T06:00:42-05:00', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'e3876ddd-e10f-4d64-97a0-553b61cdf856'	System	31 Mar 2021 11:00:48
User entered '31 Mar 2021 06:00:42'	System	31 Mar 2021 11:00:48
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-04-10T16:07:24-05:00', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'd6ee596c-f2d2-4a97-bce2-5bd51e7d77b3'	System	10 Apr 2021 21:07:37
User entered 'No (N)'	System	10 Apr 2021 21:07:37
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-04-10T16:07:28-05:00', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'd6ee596c-f2d2-4a97-bce2-5bd51e7d77b3'	System	10 Apr 2021 21:07:37
User entered 'No (N)'	System	10 Apr 2021 21:07:37
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-04-10T16:07:31-05:00', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: 'd6ee596c-f2d2-4a97-bce2-5bd51e7d77b3'	System	10 Apr 2021 21:07:37
User entered '10 Apr 2021 16:07:31'	System	10 Apr 2021 21:07:37
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-04-14T06:03:02-05:00', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '79ea127a-a463-43a8-b3bb-a5a3eef5dd9b'	System	14 Apr 2021 11:03:23
User entered 'No (N)'	System	14 Apr 2021 11:03:23
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-04-14T06:03:07-05:00', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '79ea127a-a463-43a8-b3bb-a5a3eef5dd9b'	System	14 Apr 2021 11:03:23
User entered 'No (N)'	System	14 Apr 2021 11:03:23
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-04-14T06:03:09-05:00', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '79ea127a-a463-43a8-b3bb-a5a3eef5dd9b'	System	14 Apr 2021 11:03:23
User entered '14 Apr 2021 06:03:09'	System	14 Apr 2021 11:03:23
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-04-21T06:08:20-05:00', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '0cf8667a-670b-43d6-abfc-c845c71db93d'	System	21 Apr 2021 11:08:27
User entered 'No (N)'	System	21 Apr 2021 11:08:27
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-04-21T06:08:22-05:00', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '0cf8667a-670b-43d6-abfc-c845c71db93d'	System	21 Apr 2021 11:08:27
User entered 'No (N)'	System	21 Apr 2021 11:08:27
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-04-21T06:08:24-05:00', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '0cf8667a-670b-43d6-abfc-c845c71db93d'	System	21 Apr 2021 11:08:27
User entered '21 Apr 2021 06:08:24'	System	21 Apr 2021 11:08:27
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-04-28T14:09:43-05:00', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '4bb5f3bb-6858-4d9e-9311-fd218774ba2f'	System	28 Apr 2021 21:37:42
User entered 'No (N)'	System	28 Apr 2021 21:37:42
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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 (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-04-28T14:09:45-05:00', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '4bb5f3bb-6858-4d9e-9311-fd218774ba2f'	System	28 Apr 2021 21:37:42
User entered 'No (N)'	System	28 Apr 2021 21:37:42
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-04-28T14:09:47-05:00', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '4bb5f3bb-6858-4d9e-9311-fd218774ba2f'	System	28 Apr 2021 21:37:42
User entered '28 Apr 2021 14:09:47'	System	28 Apr 2021 21:37:42
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with 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	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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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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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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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US3362023

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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US3362023

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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US3362023

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

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Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

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DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

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DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

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[Congestion](#)

Audit	User	Time (GMT)
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[Runny nose](#)

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DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Diarrhea](#)

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DataPoint Activated.	System	14 Dec 2020 19:38:51
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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
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US3362023

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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	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
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US3362023

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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US3362023

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
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US3362023

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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US3362023

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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[Body aches](#)

Audit	User	Time (GMT)
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US3362023

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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US3362023

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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US3362023

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[Date and time of submission](#)

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US3362023

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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Form: Safety Follow Up Diary

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DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3362023

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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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US3362023

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	14 Dec 2020 19:38:51
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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

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Folder: New Safety Follow Up Diary (1)

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Fever (Temperature \geq 100.4°F/38°C)

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US3362023

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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[Fatigue](#)

Audit	User	Time (GMT)
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
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US3362023

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Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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[New loss of smell](#)

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US3362023

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

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DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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[Congestion](#)

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US3362023

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

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DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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Audit	User	Time (GMT)
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US3362023

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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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US3362023

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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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
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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	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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Fever (Temperature \geq 100.4°F/38°C)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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[Fatigue](#)

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US3362023

Folder: New Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Body aches](#)

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US3362023

Folder: New Safety Follow Up Diary (1)

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[Headache](#)

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DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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[New loss of smell](#)

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Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

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[Congestion](#)

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DataPoint Activated.	System	14 Dec 2020 19:38:51
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[Runny nose](#)

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DataPoint Activated.	System	14 Dec 2020 19:38:51
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Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Vomiting](#)

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US3362023

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[Diarrhea](#)

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US3362023

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Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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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US3362023

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	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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US3362023

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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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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)

Audit	User	Time (GMT)
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Muscle aches](#)

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DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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[Runny nose](#)

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DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
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DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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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US3362023

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	14 Dec 2020 19:38:51
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US3362023

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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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US3362023

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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US3362023

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
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[Body aches](#)

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US3362023

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[Headache](#)

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US3362023

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3362023

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
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US3362023

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US3362023

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	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
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US3362023

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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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
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US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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US3362023

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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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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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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	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
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US3362023

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[Runny nose](#)

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US3362023

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[Nausea](#)

Audit	User	Time (GMT)
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
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US3362023

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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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US3362023

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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	14 Dec 2020 19:38:51
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US3362023

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

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[Body aches](#)

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DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

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Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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[Congestion](#)

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US3362023

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[Runny nose](#)

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DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
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US3362023

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US3362023

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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	14 Dec 2020 19:38:51
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US3362023

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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US3362023

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[Chills](#)

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Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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US3362023

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
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US3362023

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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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
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DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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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US3362023

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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US3362023

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3362023

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
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US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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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US3362023

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Vomiting](#)

Audit	User	Time (GMT)
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

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US3362023

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Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

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Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
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US3362023

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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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US3362023

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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	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
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US3362023

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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US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Audit	User	Time (GMT)
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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[New loss of smell](#)

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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Sore throat](#)

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DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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[Congestion](#)

Audit	User	Time (GMT)
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

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US3362023

Folder: New Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

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DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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US3362023

Folder: New Safety Follow Up Diary (1)

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

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[Date and time of submission](#)

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
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US3362023

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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	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
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US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

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Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

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[Patient Cloud Open Date & Time](#)

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DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

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DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
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US3362023

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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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
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Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

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DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Muscle aches](#)

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DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

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DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Vomiting](#)

Audit	User	Time (GMT)
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
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DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
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US3362023

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US3362023

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	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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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US3362023

Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
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[Date and time of submission](#)

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US3362023

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
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US3362023

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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US3362023

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
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US3362023

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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	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 11:58:00

US3362023

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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US3362023

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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US3362023

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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	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

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[Patient Cloud Close Date & Time](#)

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DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 11:58:00

US3362023

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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Have you been exposed to someone with 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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US3362023

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[Chills](#)

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[Cough](#)

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US3362023

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[Shortness of breath](#)

Audit	User	Time (GMT)
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US3362023

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[Difficulty breathing](#)

Audit	User	Time (GMT)
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US3362023

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[Fatigue](#)

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US3362023

Folder: New Safety Follow Up Diary (1)

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[Muscle aches](#)

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DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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[Body aches](#)

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[Headache](#)

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[New loss of taste](#)

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[New loss of smell](#)

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[Sore throat](#)

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[Congestion](#)

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[Runny nose](#)

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US3362023

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[Nausea](#)

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DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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[Vomiting](#)

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US3362023

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[Diarrhea](#)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

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TIMEPOINT

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DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 11:58:00

US3362023

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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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Have you been exposed to someone with 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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US3362023

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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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US3362023

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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US3362023

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

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US3362023

Folder: New Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
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US3362023

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[Difficulty breathing](#)

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US3362023

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[Fatigue](#)

Audit	User	Time (GMT)
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Muscle aches](#)

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Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3362023

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
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US3362023

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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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US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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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US3362023

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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US3362023

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:33:31

[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	14 Dec 2020 19:38:51
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US3362023

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US3362023

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
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US3362023

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US3362023

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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	14 Dec 2020 19:38:51
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US3362023

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

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US3362023

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

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DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
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Audit	User	Time (GMT)
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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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
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US3362023

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Difficulty breathing](#)

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DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with 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	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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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US3362023

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	14 Dec 2020 19:38:51
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US3362023

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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	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

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DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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US3362023

Folder: New Safety Follow Up Diary (1)

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3362023

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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DataPoint Activated.	System	14 Dec 2020 19:38:51
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[Date and time of submission](#)

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DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
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US3362023

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US3362023

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[Date and time of submission](#)

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US3362023

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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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US3362023

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	14 Dec 2020 19:38:51
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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	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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Fever (Temperature \geq 100.4°F/38°C)

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DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

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US3362023

Folder: New Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
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US3362023

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	14 Dec 2020 19:38:51
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US3362023

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Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Sore throat](#)

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DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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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US3362023

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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US3362023

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[Date and time of submission](#)

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US3362023

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
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US3362023

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US3362023

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	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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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US3362023

Folder: New Safety Follow Up Diary (1)

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[Headache](#)

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DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

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US3362023

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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[Congestion](#)

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US3362023

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[Runny nose](#)

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DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Vomiting](#)

Audit	User	Time (GMT)
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US3362023

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[Diarrhea](#)

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US3362023

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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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
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US3362023

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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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US3362023

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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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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)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

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Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

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[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

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Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
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[Runny nose](#)

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DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 11:58:00

US3362023

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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US3362023

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
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US3362023

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	14 Dec 2020 19:38:51
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US3362023

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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US3362023

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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[Body aches](#)

Audit	User	Time (GMT)
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DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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Folder: New Safety Follow Up Diary (1)

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
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US3362023

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US3362023

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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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Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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US3362023

Folder: New Safety Follow Up Diary (1)

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
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US3362023

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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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

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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US3362023

Folder: New Safety Follow Up Diary (1)

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

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[Date and time of submission](#)

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
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US3362023

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US3362023

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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
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US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you had 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with known SARS-CoV-2 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you experienced any 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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 11:58:00

US3362023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	14 Dec 2020 19:38:51
DataPoint Inactivated.	System	14 Dec 2020 19:24:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:58:00
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 11:58:00

US3362023

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:33:31

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)	26 Apr 2021 06:17:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-02-27T13:41:59-06:00', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '0dac2105-061b-4c1a-b7d7-74491e07113a'	System	27 Feb 2021 19:42:31
User entered 'Yes (Y)'	System	27 Feb 2021 19:42:31

US3362023

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:33:31

Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:17:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-02-27T13:42:08-06:00', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '0dac2105-061b-4c1a-b7d7-74491e07113a'	System	27 Feb 2021 19:42:31
User entered 'No (N)'	System	27 Feb 2021 19:42:31

US3362023

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:33:31

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:17:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E03B38F7-66B7-4E2F-BC94-13789834A061)', Time: '2021-02-27T13:42:19-06:00', User OID: 'PatientReportedOutcome (US3362023)', ODM File OID: '0dac2105-061b-4c1a-b7d7-74491e07113a' User entered '27 Feb 2021 19:42:19'	System	27 Feb 2021 19:42:31
	System	27 Feb 2021 19:42:31

US3362023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:14:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 14:23:51

US3362023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:14:30
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	14 Dec 2020 19:38:51
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	14 Dec 2020 19:24:21
User entered '23 Oct 2020'	(b) (4), (b) (6)	23 Oct 2020 14:23:51

US3362023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:14:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:23:51

US3362023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:14:30
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 14:23:51

US3362023

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:14:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 14:23:56

US3362023

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:11:16
User entered 'I'	System	23 Oct 2020 14:23:56

US3362023

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:15:23
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Nov 2020 17:49:50

US3362023

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:15:23
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	14 Dec 2020 19:38:51
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	14 Dec 2020 19:24:21
User entered '27 Nov 2020'	(b) (4), (b) (6)	27 Nov 2020 17:49:50

US3362023

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:15:23
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	27 Nov 2020 17:49:50

US3362023

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:15:23
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
User entered empty.	(b) (4), (b) (6)	27 Nov 2020 17:49:50

US3362023

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:15:23
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Nov 2020 17:49:53

US3362023

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:15:23
User entered 'I'	System	27 Nov 2020 17:49:53

US3362023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:15:23
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 16:32:44

US3362023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:15:23
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
User entered '28 Dec 2020'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 16:32:44

US3362023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:15:23
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 16:32:44

US3362023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:15:23
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
User entered empty.	(b) (4), (b) (6)	28 Dec 2020 16:32:44

US3362023

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:15:23
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 16:32:50

US3362023

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:15:23
User entered 'I'	System	28 Dec 2020 16:32:50

US3362023

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:15:23
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	22 Feb 2021 19:13:07

US3362023

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:15:23
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
User entered '25 Jan 2021'	Alexandra Caillouet (b) (4)	22 Feb 2021 19:13:07

US3362023

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:15:23
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
User entered 'Contact Made (CONTACT MADE)'	Alexandra Caillouet (b) (4)	22 Feb 2021 19:13:07

US3362023

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:15:23
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
User entered empty.	Alexandra Caillouet (b) (4)	22 Feb 2021 19:13:07

US3362023

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:15:23
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	22 Feb 2021 19:13:14

US3362023

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:15:23
User entered 'I'	System	22 Feb 2021 19:13:14

US3362023

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:23:44
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:10
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: It appears PPD Central Lab has a Immuno Sample (Barcode : 1F657637564) with date 22-Feb-2021 for Visit 4 Day 209; however, there is no corresponding record in EDC. Please confirm the correct visit and reconcile. Else clarify. Thank you' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: It appears PPD Central Lab has a Immuno Sample (Barcode : 1F657637564) with date 22-Feb-2021 for Visit 4 Day 209; however, there is no corresponding record in EDC. Please confirm the correct visit and reconcile. Else clarify. Thank you' answered with 'confirmed, visit 4 was performed on 22feb2021. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 06:50:31
	(b) (4), (b) (6)	23 Mar 2021 16:50:02
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: It appears PPD Central Lab has a Immuno Sample (Barcode : 1F657637564) with date 22-Feb-2021 for Visit 4 Day 209; however, there is no corresponding record in EDC. Please confirm the correct visit and reconcile. Else clarify. Thank you' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Mar 2021 08:08:23
	Alexandra Caillouet (b) (4)	22 Feb 2021 19:13:34

US3362023

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:23:44
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:10
User entered '22 Feb 2021'	Alexandra Caillouet (b) (4)	22 Feb 2021 19:13:34

US3362023

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:23:44
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:10
User entered 'Clinic (Clinic)'	Alexandra Caillouet (b) (4)	22 Feb 2021 19:13:34

US3362023

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:23:44
User entered 'VISIT4'	System	22 Feb 2021 19:13:34

US3362023

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:23:44
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:10
User entered 'No (N)'	Alexandra Caillouet (b) (4)	22 Feb 2021 19:13:41

US3362023

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:23:44
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:10
User entered empty.	Alexandra Caillouet (b) (4)	22 Feb 2021 19:13:41

US3362023

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:23:44
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:10
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	23 Mar 2021 19:02:06

US3362023

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:23:44
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:10
User entered '22 Feb 2021'	Alexandra Caillouet (b) (4)	23 Mar 2021 19:02:06

US3362023

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:23:44
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:10
User entered '12:38'	Alexandra Caillouet (b) (4)	23 Mar 2021 19:02:06

US3362023

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:23:44
User entered '22 Feb 2021 12:38'	System	23 Mar 2021 19:02:06

US3362023

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:23:44
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:10
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	22 Feb 2021 19:13:48

US3362023

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:23:44
User entered 'I'	System	22 Feb 2021 19:13:48

US3362023

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:06:17

US3362023

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:06:17

US3362023

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:06:17

US3362023

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:06:17

US3362023

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Mar 2021 21:06:45

US3362023

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Mar 2021 21:06:45

US3362023

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

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:44
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
	(b) (4)	
User entered 'Yes (Y)'	Alexandra Caillouet	25 Jan 2021 21:29:22
	(b) (4)	

US3362023

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

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:44
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
	(b) (4)	
User entered '25 Jan 2021'	Alexandra Caillouet	25 Jan 2021 21:29:22
	(b) (4)	

US3362023

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

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:44
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
	(b) (4)	
User entered 'Clinic (Clinic)'	Alexandra Caillouet	25 Jan 2021 21:29:22
	(b) (4)	

US3362023

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

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:44
User entered 'UNBLND_DECIDE'	System	25 Jan 2021 21:29:22

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

Form: Unblinding

Generated On: 11 Aug 2021 22:33:31

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:44
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
	(b) (4)	
User entered '25 Jan 2021'	Alexandra Caillouet	25 Jan 2021 21:30:30
	(b) (4)	

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

Form: Unblinding

Generated On: 11 Aug 2021 22:33:31

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:44
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:16:06

US3362023

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

Form: Unblinding

Generated On: 11 Aug 2021 22:33:31

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:44
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
	(b) (4)	
User entered 'Yes (Y)'	Alexandra Caillouet	25 Jan 2021 21:30:30
	(b) (4)	

US3362023

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

Form: Unblinding

Generated On: 11 Aug 2021 22:33:31

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:44
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
	(b) (4)	
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:16:06

US3362023

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

Form: Unblinding

Generated On: 11 Aug 2021 22:33:31

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:44
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
	(b) (4)	
User entered '25 Jan 2021'	Alexandra Caillouet	25 Jan 2021 21:30:30
	(b) (4)	

US3362023

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

Form: Unblinding

Generated On: 11 Aug 2021 22:33:31

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:44
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Alexandra Caillouet	25 Jan 2021 21:30:30
	(b) (4)	

US3362023

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

Form: Unblinding

Generated On: 11 Aug 2021 22:33:31

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:44
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Alexandra Caillouet	25 Jan 2021 21:30:30
	(b) (4)	

US3362023

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

Form: Unblinding

Generated On: 11 Aug 2021 22:33:31

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:44
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
	(b) (4)	
User entered 'Not Administered (NA)'	Alexandra Caillouet	25 Jan 2021 21:30:30
	(b) (4)	

US3362023

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

Form: Unblinding

Generated On: 11 Aug 2021 22:33:31

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:44
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
	(b) (4)	
User entered 'No (N)'	Alexandra Caillouet	25 Jan 2021 21:30:30
	(b) (4)	

US3362023

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

Form: Unblinding

Generated On: 11 Aug 2021 22:33:31

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:44
User entered empty.	System	25 Jan 2021 21:30:30

US3362023

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

Form: Unblinding

Generated On: 11 Aug 2021 22:33:31

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:44
User entered empty.	System	25 Jan 2021 21:30:30

US3362023

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:44
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
	(b) (4)	
User entered 'Yes (Y)'	Alexandra Caillouet	25 Jan 2021 21:29:32
	(b) (4)	

US3362023

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:44
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the OL-1 on 25Jan2021. Please provide accession number and tracking or clarify. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 12:19:37
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the OL-1 on 25Jan2021. Please provide accession number and tracking or clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 12:13:46
User entered '25 Jan 2021'	Alexandra Caillouet (b) (4)	25 Jan 2021 21:29:32

US3362023

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:44
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
	(b) (4)	
User entered '13:05'	Alexandra Caillouet	25 Jan 2021 21:29:32
	(b) (4)	

US3362023

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:44
User entered '25 Jan 2021 13:05'	System	25 Jan 2021 21:29:32

US3362023

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:33:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:44
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
	(b) (4)	
User entered 'Yes (Y)'	Alexandra Caillouet	25 Jan 2021 21:29:42
	(b) (4)	

US3362023

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:33:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:44
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
	(b) (4)	
User entered '25 Jan 2021'	Alexandra Caillouet	25 Jan 2021 21:29:42
	(b) (4)	

US3362023

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:33:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:44
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
	(b) (4)	
User entered '13:07'	Alexandra Caillouet	25 Jan 2021 21:29:42
	(b) (4)	

US3362023

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:44
User entered '25 Jan 2021 13:07'	System	25 Jan 2021 21:29:42

US3362023

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:33:31

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:32
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:08:35
DataPoint Verified.	(b) (4)	18 Nov 2020 20:44:50
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 20:26:24
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 14:17:49

US3362023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:08:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:45:07
User closed query 'Per DM CLR: Please review and update AE term to reflect specific type and the causative agent of this ALLERGIC REACTION. Please reconcile with the ConMed eCRF so there is an appropriate match and ensure that the field for "Was this a Solicited Adverse Reaction?" is appropriately updated.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 12:46:13
User coded data point as SOC: Gastrointestinal disorders, HLT: Tongue conditions, HLT: Tongue signs and symptoms, PT: Swollen tongue, LLT: Swelling of tongue - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 05:22:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 05:22:44
Query 'Per DM CLR: Please review and update AE term to reflect specific type and the causative agent of this ALLERGIC REACTION. Please reconcile with the ConMed eCRF so there is an appropriate match and ensure that the field for "Was this a Solicited Adverse Reaction?" is appropriately updated.' answered with 'UPDATED. NO MEDICATION REQUIRED.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 20:45:53
Data point term sent to Coder	System	24 Sep 2020 20:45:33
Coding entries removed.	(b) (4), (b) (6)	24 Sep 2020 20:45:33
User entered 'TONGUE SWELLING - POST INJECTION ALLERGIC REACTION' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:45:33
User opened query 'Per DM CLR: Please review and update AE term to reflect specific type and the causative agent of this ALLERGIC REACTION. Please reconcile with the ConMed eCRF so there is an appropriate match and ensure that the field for "Was this a Solicited Adverse Reaction?" is appropriately updated.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 01:57:30

US3362023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Allergic reaction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 20:29:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 20:29:39
Data point term sent to Coder	System	31 Aug 2020 20:29:09
User entered 'Allergic Reaction'	(b) (4), (b) (6) (b) (4)	31 Aug 2020 20:28:46

US3362023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:08:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:45:07
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 16:59:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Sep 2020 16:59:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Amy Thomassie (b) (4)	05 Sep 2020 16:59:55
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:28:46
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:28:46

US3362023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:08:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:45:07
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:45:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:28:46

US3362023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:08:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:45:07
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:28:46

US3362023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:08:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:45:07
User entered '03 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 20:28:46

US3362023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:08:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:45:07
User entered '16:20'	(b) (4), (b) (6)	31 Aug 2020 20:28:46

US3362023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 16:20'	System	31 Aug 2020 20:28:46

US3362023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:08:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:45:07
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:28:46

US3362023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:08:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:45:07
User entered '03 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 20:28:46

US3362023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:08:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:45:07
User entered '18:20'	(b) (4), (b) (6)	31 Aug 2020 20:28:46

US3362023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 18:20'	System	31 Aug 2020 20:28:46

US3362023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:08:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:45:07
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 16:59:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Sep 2020 16:59:55
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Amy Thomassie (b) (4)	05 Sep 2020 16:59:55
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:28:46
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:28:46

US3362023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:08:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:45:07
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:28:46

US3362023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:08:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:45:07
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:28:46

US3362023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:08:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:45:07
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:28:46

US3362023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:08:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:45:07
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:28:46

US3362023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:08:35
DataPoint Verified.	(b) (4)	18 Nov 2020 20:45:07
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:28:46

US3362023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:08:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:45:07
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:28:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:08:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:45:07
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:28:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:08:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:45:07
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:28:46

US3362023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:08:35
DataPoint Verified.	(b) (4)	18 Nov 2020 20:45:07
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:28:46

US3362023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:08:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:45:07
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:28:46

US3362023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:08:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:45:07
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:28:46

US3362023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:08:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:45:07
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 16:59:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Sep 2020 16:59:55
User entered 'Related (RELATED)' reason for change: Data Entry Error	Amy Thomassie (b) (4)	05 Sep 2020 16:59:55
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:28:46
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:28:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:08:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:45:07
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 16:59:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Sep 2020 16:59:55
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Amy Thomassie (b) (4)	05 Sep 2020 16:59:55
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:28:46
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:28:46

US3362023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:08:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:45:07
User closed query 'Per CDM re-query: Thank you for your answer. Since subject discontinued dosing then please consider completing "Dosing Discontinuation" form under "End of Study". Thank you!' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 06:21:08
Query 'Per CDM re-query: Thank you for your answer. Since subject discontinued dosing then please consider completing "Dosing Discontinuation" form under "End of Study". Thank you!' answered with 'subject remains in study. If the dosing discontinuation form is completed then additional data points cannot be collected. ' (Site from DM).	Amy Thomassie (b) (4)	01 Oct 2020 10:53:50
	(b) (4)	
User opened query 'Per CDM re-query: Thank you for your answer. Since subject discontinued dosing then please consider completing "Dosing Discontinuation" form under "End of Study". Thank you!' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 06:13:38
User closed query 'Per CDM: Since subject withdrawn from the study, then please kindly consider completing "End of Study" forms. Thank you!' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 09:48:09
Query 'Per CDM: Since subject withdrawn from the study, then please kindly consider completing "End of Study" forms. Thank you!' answered with 'Patient continuing in study, but without 2nd injection. IP only was withdrawn at V2 Day 29. Patient still completing safety phone calls and safety visits.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 20:13:28
User opened query 'Per CDM: Since subject withdrawn from the study, then please kindly consider completing "End of Study" forms. Thank you!' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 11:12:36
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 16:59:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Sep 2020 16:59:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Amy Thomassie (b) (4) (b) (4)	05 Sep 2020 16:59:55
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:28:46
User entered empty.	(b) (4), (b) (6) (b) (4)	31 Aug 2020 20:28:46

US3362023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

None

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:08:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:45:07
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	05 Sep 2020 16:59:55
User entered '1' reason for change: Data Entry Error	Amy Thomassie (b) (4)	05 Sep 2020 16:59:55
	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	31 Aug 2020 20:28:46
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:28:46

US3362023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:08:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:45:07
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:28:46

US3362023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:08:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:45:07
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:28:46

US3362023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:08:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:45:07
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 16:59:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Sep 2020 16:59:55
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Amy Thomassie (b) (4)	05 Sep 2020 16:59:55
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:28:46
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:28:46

US3362023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:08:35
DataPoint Verified.	(b) (4)	18 Nov 2020 20:45:07
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:28:46

US3362023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:08:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:45:07
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:28:46

US3362023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	31 Aug 2020 20:28:46

US3362023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 16:59:55

US3362023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:45:57
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:25:14
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' answered with 'patient reports no recent injections, updated medical history- marked as start date as completely unknown' (Site from DM).	Crystal Rowell (b) (4) (b) (4)	30 Mar 2021 21:32:20
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 09:50:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 17:43:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:45:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION HYDROCHLORIDE, PRODUCTSYNONYM: WELLBUTRIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	27 Aug 2020 17:54:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:54:55
Data point term sent to Coder	System	26 Aug 2020 17:47:33
User entered 'WELLBUTRIN'	(b) (4), (b) (6)	26 Aug 2020 17:46:40

US3362023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:45:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 17:46:40

US3362023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:45:57
User entered 'DEPRESSION'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 17:46:40

US3362023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:45:57
User entered '300'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 17:46:40

US3362023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:45:57
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 17:46:40

US3362023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:45:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 17:46:40

US3362023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:45:57
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 17:46:40

US3362023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:45:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 17:46:40

US3362023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:45:57
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 17:46:40

US3362023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:45:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 17:46:40

US3362023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:45:57
User entered 'UN UNK 2000'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 17:46:40

US3362023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:45:57
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 17:46:40

US3362023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:45:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 17:46:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:45:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 17:46:40

US3362023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:45:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 17:46:40

US3362023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 17:46:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 17:46:40

US3362023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 17:46:40

US3362023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:33:31

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:45:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:17:58

US3362023

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:33:31

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:54:04
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
User entered '03 Aug 2020' reason for change: Data Entry Error	Amy Thomassie (b) (4)	17 Oct 2020 16:41:03
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	18 Sep 2020 08:46:14
Query 'Data is required. Please complete.' answered with 'removed discontinuation end of study entry due to subject only holding dose for injection 2; subject is still in study' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 13:42:46
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 13:41:25
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 13:41:25
User entered '03 Aug 2020'	Amy Thomassie (b) (4)	12 Sep 2020 12:00:05

US3362023

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:33:31

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:54:04
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	Amy Thomassie (b) (4)	17 Oct 2020 16:41:03
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	18 Sep 2020 08:46:15
User closed query 'PER DM REQUERY: Thank you for the response.However,as per response'subject was not dosed due to an allergic reaction; subject is still continuing with study just was not dosed on day 2,but 'Primary reasaon for dosing discontinuation is given as 'Ae' and 'allergic Reaction.If subject is continuing the study please consider to remove data from study discontinuation form.Please review and update data appropriately else clarify.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 05:39:52
Query 'Data is required. Please complete.' answered with 'removed discontinuation end of study entry due to subject only holding dose for injection 2; subject is still in study' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 13:42:43
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 13:41:25
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 13:41:25
Query 'PER DM REQUERY: Thank you for the response.However,as per response'subject was not dosed due to an allergic reaction; subject is still continuing with study just was not dosed on day 2,but 'Primary reasaon for dosing discontinuation is given as 'Ae' and 'allergic Reaction.If subject is continuing the study please consider to remove data from study discontinuation form.Please review and update data appropriately else clarify.' answered with 'data removed from discontinuation form' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 13:41:18

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:33:31

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User opened query 'PER DM REQUERY: Thank you for the response.However,as per response'subject was not dosed due to an allergic reaction; subject is still continuing with study just was not dosed on day 2,but 'Primary reasaon for dosing discontinuation is given as 'Ae' and 'allergic Reaction.If subject is continuing the study please consider to remove data from study discontinuation form.Please review and update data appropriately else clarify.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 05:34:55
User closed query 'Per DMR: Primary reason for dosing discontinuation is recorded as 'Due to AE',However, no data is recorded on 'End of Study / Study Discontinuation'form. Kindly verify and consider to update the form else clarify.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 05:34:55
Query 'Per DMR: Primary reason for dosing discontinuation is recorded as 'Due to AE',However, no data is recorded on 'End of Study / Study Discontinuation'form. Kindly verify and consider to update the form else clarify.' answered with 'subject was not dosed due to an allergic reaction; subject is still continuing with study just was not dosed on day 2' (Site from DM).	Crystal Rowell (b) (4)	16 Sep 2020 21:49:19
User opened query 'Per DMR: Primary reason for dosing discontinuation is recorded as 'Due to AE',However, no data is recorded on 'End of Study / Study Discontinuation'form. Kindly verify and consider to update the form else clarify.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 12:30:27
User entered 'AE (specify) (ADVERSE EVENT)'	Amy Thomassie (b) (4)	12 Sep 2020 12:00:05

US3362023

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:33:31

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 12:54:04
User signature succeeded.	Jordan Whatley (b) (4)	23 Apr 2021 23:54:00
User closed query 'Per CDM: Per sponsor review, please update specify field to include both AE, number sign, and number. (i.e. AE #1).' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 17:47:40
Query 'Per CDM: Per sponsor review, please update specify field to include both AE, number sign, and number. (i.e. AE #1).' answered with 'updated' (Site from DM).	Amy Thomassie (b) (4)	03 Mar 2021 21:34:41
DataPoint Un-verified.	Amy Thomassie (b) (4)	03 Mar 2021 21:34:33
User entered 'AE # 1' reason for change: Data Entry Error	Amy Thomassie (b) (4)	03 Mar 2021 21:34:33
User opened query 'Per CDM: Per sponsor review, please update specify field to include both AE, number sign, and number. (i.e. AE #1).' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 19:40:21
User closed query 'Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 23:14:49
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:44:39
Query 'Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details' answered with 'updated' (Site from DM).	Crystal Rowell (b) (4)	18 Nov 2020 16:13:36
User entered 'AE1' reason for change: Data Entry Error	Crystal Rowell (b) (4)	18 Nov 2020 16:13:29
User opened query 'Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 15:00:19
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	17 Oct 2020 16:43:20

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
User entered 'TONGUE SWELLING - POST INJECTION #1 ALLERGIC REACTION. subject will continue in study without receiving injection #2' reason for change: Data Entry Error	Amy Thomassie (b) (4)	17 Oct 2020 16:43:20
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	17 Oct 2020 16:41:03
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 13:41:25
User entered 'Allergic reaction'	Amy Thomassie (b) (4)	12 Sep 2020 12:00:05