

US3032201 (Prod: Meridian Clinical Research (Norfolk-Nebraska))

Generated By: KC Joubran

Generated On: 11 Aug 2021 21:52:11

All time stamps listed in this document are displayed in GMT

US3032201

Form: Participant Creation

Data signed: (b) (4) 28 Sep 2020 17:33:28

Generated On: 11 Aug 2021 21:52:11

[Participant ID](#)

US3032201

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

US3032201

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 17:33:29

Generated On: 11 Aug 2021 21:52:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 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

US3032201

Folder: Screening

Form: Demographics

Data signed: (b) (4) 28 Sep 2020 17:33:29

Generated On: 11 Aug 2021 21:52:11

Date of Birth (MMM yyyy)	(b) (6)	1982
Age		38
Age Units		YEARS
Age (Derived)		38
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) 28 Sep 2020 17:33:29

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Date of Informed Consent (<i>dd MMM yyyy</i>)	12 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3032201

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 28 Sep 2020 17:33:29

Generated On: 11 Aug 2021 21:52:11

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3032201

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 28 Sep 2020 17:33:29

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 28 Sep 2020 17:33:29

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Condition	SEASONAL ALLERGIES-NO MEDICATION TAKEN
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 08 Oct 2020 15:35:45

Generated On: 11 Aug 2021 21:52:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	17:45 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 17:45
Height (<i>xxx.x</i>)	172.7 cm
Weight (<i>xxx.x</i>)	92.0 kg
BMI (<i>xxx.x</i>)	30.84631 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) 28 Sep 2020 17:33:29

Generated On: 11 Aug 2021 21:52:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 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) 28 Sep 2020 17:33:29

Generated On: 11 Aug 2021 21:52:11

Date of assessment (*dd MMM yyyy*) 12 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*) _____
Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 28 Sep 2020 17:33:29

Generated On: 11 Aug 2021 21:52:11

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 12 AUG 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

Collection date _____
Collection time _____
Collection date and time (derived) _____

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Sep 2020 17:33:29

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Sep 2020 17:33:29

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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)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 17:33:30

Generated On: 11 Aug 2021 21:52:11

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

Visit date (dd MMM yyyy)	12 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 02 Nov 2020 22:10:16

Generated On: 11 Aug 2021 21:52:11

What was the date of randomization? (dd MMM yyyy) 12 AUG 2020

What was the participant's randomization number? 103573

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Oct 2020 13:55:13

Generated On: 11 Aug 2021 21:52:11

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Oct 2020 13:55:13

Generated On: 11 Aug 2021 21:52:11

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)	12 AUG 2020
Time of assessment (00:00-23:59)	17:45 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 17:45
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)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Oct 2020 13:55:13

Generated On: 11 Aug 2021 21:52:11

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)	12 AUG 2020
Time of assessment (00:00-23:59)	19:19 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 19:19
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)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 17:33:30

Generated On: 11 Aug 2021 21:52:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 28 Oct 2020 16:37:26

Generated On: 11 Aug 2021 21:52:11

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 28 Sep 2020 17:33:29

Generated On: 11 Aug 2021 21:52:11

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) 12 AUG 2020

What was the treatment time? (00:00-23:59) 18:43 (24 HR)

Treatment Date and Time (derived) 12 AUG 2020 18:43

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) 28 Sep 2020 17:33:30

Generated On: 11 Aug 2021 21:52:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 AUG 2020

Collection time (00:00-23:59)

18:18 (24 HR)

Collection date and time (derived)

12 AUG 2020 18:18

US3032201

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Sep 2020 17:33:29

Generated On: 11 Aug 2021 21:52:11

Collection date (dd MMM yyyy)			12 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:01	12 AUG 2020 16:01
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:33:29

Generated On: 11 Aug 2021 21:52:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 19:11

PC Open Date & Time

12 AUG 2020 19:03

PC Close Date & Time

12 AUG 2020 21:33

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

12 AUG 2020 22:28

PC Close Date & Time

13 AUG 2020 11:59

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 19:00

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.6 °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

14 AUG 2020 20:46

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 21:52

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 19:57

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 21:05

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 19:53

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

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

12 AUG 2020 19:11

PC Open Date & Time

12 AUG 2020 19:03

PC Close Date & Time

12 AUG 2020 21:33

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

12 AUG 2020 22:28

PC Close Date & Time

13 AUG 2020 11:59

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:52:11

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

13 AUG 2020 18:58

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:52:11

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

14 AUG 2020 20:47

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:52:11

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

15 AUG 2020 21:52

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:52:11

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

16 AUG 2020 19:56

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:52:11

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

17 AUG 2020 21:05

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 19:52

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

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 ☐

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

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

No ☒

Yes ☐

PC Time stamp	12 AUG 2020 19:12
PC Open Date & Time	12 AUG 2020 19:03
PC Close Date & Time	12 AUG 2020 21:33

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

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 ☐

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

12 AUG 2020 22:28

PC Close Date & Time

13 AUG 2020 11:59

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:11

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 ☒

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:11

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 18:58
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:11

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 ☒

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:11

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 20:47
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:11

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 ☒

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:11

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 21:53
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:11

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 ☒

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:11

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 19:57
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:11

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 ☒

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:11

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 21:06
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:11

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 ☒

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:11

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 19:53
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3032201

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 17:33:29

Generated On: 11 Aug 2021 21:52:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032201

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:33:29

Generated On: 11 Aug 2021 21:52:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032201

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 17:33:28

Generated On: 11 Aug 2021 21:52:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032201

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:33:28

Generated On: 11 Aug 2021 21:52:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032201

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 17:33:28

Generated On: 11 Aug 2021 21:52:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032201

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:33:28

Generated On: 11 Aug 2021 21:52:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032201

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 17:33:30

Generated On: 11 Aug 2021 21:52:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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	VISIT2

US3032201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Sep 2020 17:33:30

Generated On: 11 Aug 2021 21:52:11

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)	10 SEP 2020
Time of assessment (00:00-23:59)	14:47 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 14:47
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)	93 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3032201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Sep 2020 17:33:30

Generated On: 11 Aug 2021 21:52:11

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)	10 SEP 2020
Time of assessment (00:00-23:59)	16:22 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 16:22
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3032201

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 17:33:30

Generated On: 11 Aug 2021 21:52:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

US3032201

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 28 Sep 2020 17:33:30

Generated On: 11 Aug 2021 21:52:11

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (dd MMM yyyy)	10 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3032201

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 28 Sep 2020 17:33:30

Generated On: 11 Aug 2021 21:52:11

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) 10 SEP 2020

What was the treatment time? (00:00-23:59) 15:50 (24 HR)

Treatment Date and Time (derived) 10 SEP 2020 15:50

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

US3032201

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Sep 2020 17:33:30

Generated On: 11 Aug 2021 21:52:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

10 SEP 2020

Collection time (00:00-23:59)

15:19 (24 HR)

Collection date and time (derived)

10 SEP 2020 15:19

US3032201

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Sep 2020 17:33:30

Generated On: 11 Aug 2021 21:52:11

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:09	10 SEP 2020 15:09
Nasopharyngeal Swab 2	No		

US3032201

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:33:30

Generated On: 11 Aug 2021 21:52:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

10 SEP 2020 16:22

PC Open Date & Time

10 SEP 2020 16:10

PC Close Date & Time

10 SEP 2020 18:40

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.8 °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	10 SEP 2020 20:05
PC Open Date & Time	10 SEP 2020 19:35
PC Close Date & Time	11 SEP 2020 11:59

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:52:11

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

96.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 01:23

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.1 °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

12 SEP 2020 21:43

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 23:00

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:52:11

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

96.6 °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

14 SEP 2020 23:53

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:52:11

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

15 SEP 2020 20:29

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.6 °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

16 SEP 2020 22:01

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 16:23

PC Open Date & Time

10 SEP 2020 16:10

PC Close Date & Time

10 SEP 2020 18:40

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

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

10 SEP 2020 20:05

PC Open Date & Time

10 SEP 2020 19:35

PC Close Date & Time

11 SEP 2020 11:59

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 01:23

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:52:11

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

12 SEP 2020 21:43

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:52:11

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

13 SEP 2020 23:00

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:52:11

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

14 SEP 2020 23:53

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:52:11

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

15 SEP 2020 20:29

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 22:01

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

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 ☐

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 16:23
PC Open Date & Time	10 SEP 2020 16:10
PC Close Date & Time	10 SEP 2020 18:40

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

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 ☐

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 20:06
PC Open Date & Time	10 SEP 2020 19:35
PC Close Date & Time	11 SEP 2020 11:59

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:11

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 ☒

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:11

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 01:24
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:11

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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US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:11

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 21:44
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:11

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 ☒

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:11

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 23:01
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:11

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 ☒

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:11

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 23:54
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:11

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 ☒

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:11

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 20:30
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:11

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 ☒

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:11

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 22:02
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3032201

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 17:33:28

Generated On: 11 Aug 2021 21:52:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032201

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:33:28

Generated On: 11 Aug 2021 21:52:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032201

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 17:33:28

Generated On: 11 Aug 2021 21:52:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032201

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:33:28

Generated On: 11 Aug 2021 21:52:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032201

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 05 Oct 2020 16:17:11

Generated On: 11 Aug 2021 21:52:11

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3032201

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 05 Oct 2020 16:17:11

Generated On: 11 Aug 2021 21:52:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032201

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Oct 2020 14:51:16

Generated On: 11 Aug 2021 21:52:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3032201

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Oct 2020 14:51:16

Generated On: 11 Aug 2021 21:52:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 OCT 2020
Time of assessment (00:00-23:59)	07:58 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 07:58
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3032201

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Oct 2020 14:51:16

Generated On: 11 Aug 2021 21:52:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 OCT 2020

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

US3032201

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Oct 2020 14:51:16

Generated On: 11 Aug 2021 21:52:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 OCT 2020

Collection time (00:00-23:59)

08:14 (24 HR)

Collection date and time (derived)

15 OCT 2020 08:14

US3032201

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 22 Oct 2020 14:51:16

Generated On: 11 Aug 2021 21:52:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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	13 OCT 2020 17:08:33
Patient Cloud Open Date & Time	12 OCT 2020 00:01
Patient Cloud Close Date & Time	16 OCT 2020 23:59

US3032201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

19 OCT 2020 06:51:26

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3032201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 OCT 2020 05:44:36

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3032201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 NOV 2020 06:31:19

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3032201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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	18 NOV 2020 08:29:08
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

DAY 103

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

No ☒

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

24 NOV 2020 16:33:14

Patient Cloud Open Date & Time

20 NOV 2020 00:01

Patient Cloud Close Date & Time

24 NOV 2020 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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 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	27 NOV 2020 00:40:46
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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	06 DEC 2020 19:16:24
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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	11 DEC 2020 07:23:46
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 DEC 2020 05:27:40

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

27 DEC 2020 19:10:19

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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	05 JAN 2021 10:57:47
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 JAN 2021 17:40:08

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 JAN 2021 07:25:29

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

01 FEB 2021 10:04:04

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 FEB 2021 06:02:46
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

12 FEB 2021 06:43:33

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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	22 FEB 2021 21:29:05
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

05 MAR 2021 06:30:51

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 MAR 2021 22:38:56

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

23 MAR 2021 17:32:34

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 MAR 2021 02:32:33

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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	02 APR 2021 00:03:48
Patient Cloud Open Date & Time	02 APR 2021 00:01
Patient Cloud Close Date & Time	06 APR 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 00:56:32

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

16 APR 2021 11:22:23

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

23 APR 2021 07:04:36

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

30 APR 2021 07:31:58

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

07 MAY 2021 00:01

Patient Cloud Close Date & Time

11 MAY 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

14 MAY 2021 00:01

Patient Cloud Close Date & Time

18 MAY 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

21 MAY 2021 00:01

Patient Cloud Close Date & Time

25 MAY 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

28 MAY 2021 00:01

Patient Cloud Close Date & Time

01 JUN 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

04 JUN 2021 00:01

Patient Cloud Close Date & Time

08 JUN 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

11 JUN 2021 00:01

Patient Cloud Close Date & Time

15 JUN 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 JUN 2021 00:01

Patient Cloud Close Date & Time

22 JUN 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

25 JUN 2021 00:01

Patient Cloud Close Date & Time

29 JUN 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

02 JUL 2021 00:01

Patient Cloud Close Date & Time

06 JUL 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

09 JUL 2021 00:01

Patient Cloud Close Date & Time

13 JUL 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

16 JUL 2021 00:01

Patient Cloud Close Date & Time

20 JUL 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

23 JUL 2021 00:01

Patient Cloud Close Date & Time

27 JUL 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

30 JUL 2021 00:01

Patient Cloud Close Date & Time

03 AUG 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

06 AUG 2021 00:01

Patient Cloud Close Date & Time

10 AUG 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

13 AUG 2021 00:01

Patient Cloud Close Date & Time

17 AUG 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

20 AUG 2021 00:01

Patient Cloud Close Date & Time

24 AUG 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

27 AUG 2021 00:01

Patient Cloud Close Date & Time

31 AUG 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

03 SEP 2021 00:01

Patient Cloud Close Date & Time

07 SEP 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT	DAY 397
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

10 SEP 2021 00:01

Patient Cloud Close Date & Time

14 SEP 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 SEP 2021 00:01

Patient Cloud Close Date & Time

21 SEP 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

24 SEP 2021 00:01

Patient Cloud Close Date & Time

28 SEP 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

01 OCT 2021 00:01

Patient Cloud Close Date & Time

05 OCT 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

08 OCT 2021 00:01

Patient Cloud Close Date & Time

12 OCT 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

15 OCT 2021 00:01

Patient Cloud Close Date & Time

19 OCT 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

22 OCT 2021 00:01

Patient Cloud Close Date & Time

26 OCT 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

29 OCT 2021 00:01

Patient Cloud Close Date & Time

02 NOV 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

05 NOV 2021 00:01

Patient Cloud Close Date & Time

09 NOV 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

12 NOV 2021 00:01

Patient Cloud Close Date & Time

16 NOV 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 NOV 2021 00:01

Patient Cloud Close Date & Time

23 NOV 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

26 NOV 2021 00:01

Patient Cloud Close Date & Time

30 NOV 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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 DEC 2021 00:01

Patient Cloud Close Date & Time

07 DEC 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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 DEC 2021 00:01

Patient Cloud Close Date & Time

14 DEC 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 DEC 2021 00:01

Patient Cloud Close Date & Time

21 DEC 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

24 DEC 2021 00:01

Patient Cloud Close Date & Time

28 DEC 2021 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

31 DEC 2021 00:01

Patient Cloud Close Date & Time

04 JAN 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

07 JAN 2022 00:01

Patient Cloud Close Date & Time

11 JAN 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

14 JAN 2022 00:01

Patient Cloud Close Date & Time

18 JAN 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

21 JAN 2022 00:01

Patient Cloud Close Date & Time

25 JAN 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

28 JAN 2022 00:01

Patient Cloud Close Date & Time

01 FEB 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

04 FEB 2022 00:01

Patient Cloud Close Date & Time

08 FEB 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

11 FEB 2022 00:01

Patient Cloud Close Date & Time

15 FEB 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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="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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 FEB 2022 00:01

Patient Cloud Close Date & Time

22 FEB 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

25 FEB 2022 00:01

Patient Cloud Close Date & Time

01 MAR 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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 MAR 2022 00:01

Patient Cloud Close Date & Time

08 MAR 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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 MAR 2022 00:01

Patient Cloud Close Date & Time

15 MAR 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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 MAR 2022 00:01

Patient Cloud Close Date & Time

22 MAR 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

25 MAR 2022 00:01

Patient Cloud Close Date & Time

29 MAR 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

01 APR 2022 00:01

Patient Cloud Close Date & Time

05 APR 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

08 APR 2022 00:01

Patient Cloud Close Date & Time

12 APR 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

15 APR 2022 00:01

Patient Cloud Close Date & Time

19 APR 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

22 APR 2022 00:01

Patient Cloud Close Date & Time

26 APR 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

29 APR 2022 00:01

Patient Cloud Close Date & Time

03 MAY 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

06 MAY 2022 00:01

Patient Cloud Close Date & Time

10 MAY 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

13 MAY 2022 00:01

Patient Cloud Close Date & Time

17 MAY 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

20 MAY 2022 00:01

Patient Cloud Close Date & Time

24 MAY 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

27 MAY 2022 00:01

Patient Cloud Close Date & Time

31 MAY 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

03 JUN 2022 00:01

Patient Cloud Close Date & Time

07 JUN 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

10 JUN 2022 00:01

Patient Cloud Close Date & Time

14 JUN 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT	DAY 677
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 JUN 2022 00:01

Patient Cloud Close Date & Time

21 JUN 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

24 JUN 2022 00:01

Patient Cloud Close Date & Time

28 JUN 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

01 JUL 2022 00:01

Patient Cloud Close Date & Time

05 JUL 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

08 JUL 2022 00:01

Patient Cloud Close Date & Time

12 JUL 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

15 JUL 2022 00:01

Patient Cloud Close Date & Time

19 JUL 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

22 JUL 2022 00:01

Patient Cloud Close Date & Time

26 JUL 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

29 JUL 2022 00:01

Patient Cloud Close Date & Time

02 AUG 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

05 AUG 2022 00:01

Patient Cloud Close Date & Time

09 AUG 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

12 AUG 2022 00:01

Patient Cloud Close Date & Time

16 AUG 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 AUG 2022 00:01

Patient Cloud Close Date & Time

23 AUG 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

26 AUG 2022 00:01

Patient Cloud Close Date & Time

30 AUG 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

02 SEP 2022 00:01

Patient Cloud Close Date & Time

06 SEP 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

09 SEP 2022 00:01

Patient Cloud Close Date & Time

13 SEP 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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"/>

US3032201

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

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

Date and time of submission

Patient Cloud Open Date & Time

16 SEP 2022 00:01

Patient Cloud Close Date & Time

20 SEP 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3032201

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.

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

Date and time of submission

Patient Cloud Open Date & Time

23 SEP 2022 00:01

Patient Cloud Close Date & Time

27 SEP 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

30 SEP 2022 00:01

Patient Cloud Close Date & Time

04 OCT 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

07 OCT 2022 00:01

Patient Cloud Close Date & Time

11 OCT 2022 23:59

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

14 OCT 2022 00:01

Patient Cloud Close Date & Time

18 OCT 2022 23:59

US3032201

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 21:52:11

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		03 MAR 2021 07:18:59

US3032201

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 24 Nov 2020 20:28:43

Generated On: 11 Aug 2021 21:52:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032201

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Nov 2020 21:37:10

Generated On: 11 Aug 2021 21:52:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032201

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Dec 2020 15:54:32

Generated On: 11 Aug 2021 21:52:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032201

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Dec 2020 15:54:32

Generated On: 11 Aug 2021 21:52:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032201

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 18 Jan 2021 19:29:22

Generated On: 11 Aug 2021 21:52:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032201

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 18 Jan 2021 19:29:22

Generated On: 11 Aug 2021 21:52:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032201

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:56:04

Generated On: 11 Aug 2021 21:52:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032201

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:56:04

Generated On: 11 Aug 2021 21:52:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032201

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 15:38:15

Generated On: 11 Aug 2021 21:52:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3032201

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 15:38:15

Generated On: 11 Aug 2021 21:52:11

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3032201

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 15:38:15

Generated On: 11 Aug 2021 21:52:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 MAR 2021

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

US3032201

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 15:38:15

Generated On: 11 Aug 2021 21:52:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 MAR 2021

Collection time (00:00-23:59)

09:15 (24 HR)

Collection date and time (derived)

25 MAR 2021 09:15

US3032201

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 15:38:15

Generated On: 11 Aug 2021 21:52:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032201

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 18:07:28

Generated On: 11 Aug 2021 21:52:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032201

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 18:07:28

Generated On: 11 Aug 2021 21:52:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032201

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

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

US3032201

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3032201

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:52:11

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"/>

US3032201

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 21:52:11

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3032201

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

Form: Visit Date

Data signed: (b) (4) 30 Jan 2021 16:50:59

Generated On: 11 Aug 2021 21:52:11

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

Visit date (dd MMM yyyy)	21 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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US3032201

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

Form: Unblinding

Data signed: (b) (4) 18 Mar 2021 21:15:39

Generated On: 11 Aug 2021 21:52:11

Date of updated informed consent (<i>dd MMM yyyy</i>)	21 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	21 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3032201

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 30 Jan 2021 16:50:59

Generated On: 11 Aug 2021 21:52:11

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

US3032201

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 30 Jan 2021 16:50:59

Generated On: 11 Aug 2021 21:52:11

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 JAN 2021
Time of assessment (00:00-23:59)	11:05 (24 HR)
Vital Signs Date and Time (derived)	21 JAN 2021 11:05
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3032201

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 30 Jan 2021 16:50:59

Generated On: 11 Aug 2021 21:52:11

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 JAN 2021
Time of assessment (00:00-23:59)	12:13 (24 HR)
Vital Signs Date and Time (derived)	21 JAN 2021 12:13
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)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3032201

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

Form: Physical Examination

Data signed: (b) (4) 30 Jan 2021 16:50:59

Generated On: 11 Aug 2021 21:52:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 JAN 2021

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

US3032201

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

Form: Pregnancy Test

Data signed: (b) (4) 30 Jan 2021 16:50:59

Generated On: 11 Aug 2021 21:52:11

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (dd MMM yyyy)	21 JAN 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3032201

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

Form: Exposure

Data signed: (b) (4) 30 Jan 2021 16:50:59

Generated On: 11 Aug 2021 21:52:11

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 21 JAN 2021

What was the treatment time? (00:00-23:59) 11:39 (24 HR)

Treatment Date and Time (derived) 21 JAN 2021 11:39

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

US3032201

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 30 Jan 2021 16:50:59

Generated On: 11 Aug 2021 21:52:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 JAN 2021

Collection time (00:00-23:59)

10:41 (24 HR)

Collection date and time (derived)

21 JAN 2021 10:41

US3032201

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 30 Jan 2021 16:50:59

Generated On: 11 Aug 2021 21:52:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 JAN 2021
Collection time (00:00 - 23:59)	10:46
Collection Date and Time (derived)	21 JAN 2021 10:46

US3032201

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

Form: Continuing

Data signed: (b) (4) 30 Jan 2021 16:50:59

Generated On: 11 Aug 2021 21:52:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032201

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 17:25:31

Generated On: 11 Aug 2021 21:52:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032201

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:25:31

Generated On: 11 Aug 2021 21:52:11

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

US3032201

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 17:25:31

Generated On: 11 Aug 2021 21:52:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 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	OLD29

US3032201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 17:25:31

Generated On: 11 Aug 2021 21:52:11

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 FEB 2021
Time of assessment (00:00-23:59)	14:36 (24 HR)
Vital Signs Date and Time (derived)	18 FEB 2021 14:36
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3032201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 17:25:31

Generated On: 11 Aug 2021 21:52:11

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	

US3032201

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 17:25:31

Generated On: 11 Aug 2021 21:52:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 FEB 2021

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

US3032201

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 22 Feb 2021 17:25:31

Generated On: 11 Aug 2021 21:52:11

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (dd MMM yyyy)	18 FEB 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input checked="" type="radio"/>
	Negative <input type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3032201

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 19 Apr 2021 15:26:39

Generated On: 11 Aug 2021 21:52:11

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 16 APR 2021

What was the treatment time? (00:00-23:59) 11:39 (24 HR)

Treatment Date and Time (derived) 16 APR 2021 11:39

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

US3032201

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:25:31

Generated On: 11 Aug 2021 21:52:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032201

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Apr 2021 19:37:17

Generated On: 11 Aug 2021 21:52:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032201

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:15:39

Generated On: 11 Aug 2021 21:52:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032201

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 15:38:15

Generated On: 11 Aug 2021 21:52:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3032201

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 15:38:15

Generated On: 11 Aug 2021 21:52:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 MAR 2021
Time of assessment (00:00-23:59)	09:59 (24 HR)
Vital Signs Date and Time (derived)	30 MAR 2021 09:59
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)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3032201

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 15:38:15

Generated On: 11 Aug 2021 21:52:11

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.

US3032201

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 15:38:15

Generated On: 11 Aug 2021 21:52:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 MAR 2021

Collection time (00:00-23:59)

10:04 (24 HR)

Collection date and time (derived)

30 MAR 2021 10:04

US3032201

Folder: Unscheduled 16 Apr 2021

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 19 Apr 2021 15:26:40

Generated On: 11 Aug 2021 21:52:11

Visit Date	16 APR 2021
Please check all assessments that apply for this visit	
Physical Exam	True
Vital Signs	True
Immunogenicity Assessment	True
Pregnancy Test	True

US3032201

Folder: Unscheduled 16 Apr 2021

Form: Vital Signs

Data signed: (b) (4) 19 Apr 2021 15:26:40

Generated On: 11 Aug 2021 21:52:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	16 APR 2021
Time of assessment (<i>00:00-23:59</i>)	10:33 (24 HR)
Vital Signs Date and Time (derived)	16 APR 2021 10:33
Temperature (<i>xxx.x</i>)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	77 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3032201

Folder: Unscheduled 16 Apr 2021

Form: Physical Examination

Data signed: (b) (4) 19 Apr 2021 15:26:39

Generated On: 11 Aug 2021 21:52:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 APR 2021

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

US3032201

Folder: Unscheduled 16 Apr 2021

Form: Pregnancy Test

Data signed: (b) (4) 19 Apr 2021 15:26:40

Generated On: 11 Aug 2021 21:52:11

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	16 APR 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	16 APR 2021
Collection time	10:27
Collection date and time (derived)	16 APR 2021 10:27

US3032201

Folder: **Unscheduled 16 Apr 2021**

Form: **Immunogenicity Assessment**

Data signed: (b) (4) **19 Apr 2021 15:26:39**

Generated On: **11 Aug 2021 21:52:11**

Was the sample collected?

Yes ☐

No ☒

Collection date (*dd MMM yyyy*)

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

Collection date and time (derived)

US3032201

Folder: **Unscheduled 23 Apr 2021**

Form: **Unscheduled Visit Assessment**

Data signed: (b) (4) 23 Apr 2021 19:37:17

Generated On: 11 Aug 2021 21:52:11

Visit Date

Please check all assessments that apply for this visit

Physical Exam	False
Vital Signs	False
Immunogenicity Assessment	False
Pregnancy Test	False

US3032201

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 22 Feb 2021 17:25:31

Generated On: 11 Aug 2021 21:52:11

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3032201

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 06 Apr 2021 15:38:15

Generated On: 11 Aug 2021 21:52:11

AEID	USA-US032-2021-MRNA-1273-P30 1000009
Adverse event	PREGNANCY
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	01 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	26 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 06 Apr 2021 15:38:15

Generated On: 11 Aug 2021 21:52:11

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

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Oct 2020 16:37:26

Generated On: 11 Aug 2021 21:52:11

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

Yes ☒

No ☐

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

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 18:07:28

Generated On: 11 Aug 2021 21:52:11

Name of Medication SEASONAL INFLUENZA
VACCINE

Prophylaxis Yes ☒
No ☐

Indication SEASONAL INFLUENZA
PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 18:07:28

Generated On: 11 Aug 2021 21:52:11

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

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 18:07:28

Generated On: 11 Aug 2021 21:52:11

Name of Medication LEVONORGESTREL

Prophylaxis Yes ☐
No ☒

Indication PREGNANCY

Dose per administration 1.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 18:07:28

Generated On: 11 Aug 2021 21:52:11

	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)		01 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 18:07:28

Generated On: 11 Aug 2021 21:52:11

Name of Medication LEVONORGESTREL

Prophylaxis Yes ☐
No ☒

Indication PREGNANCY

Dose per administration 1.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 18:07:28

Generated On: 11 Aug 2021 21:52:11

	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)		03 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 03 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 18:07:28

Generated On: 11 Aug 2021 21:52:11

Name of Medication DEPO-PROVERA
(MEDROXYPROGESTERONE)

Prophylaxis Yes ☒
No ☐

Indication CONTRACEPTION

Dose per administration 150

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

EVERY THREE MONTHS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 18:07:28

Generated On: 11 Aug 2021 21:52:11

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input checked="" 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)		8 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3032201

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Sep 2020 17:33:28

Generated On: 11 Aug 2021 21:52:11

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3032201

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 06 Apr 2021 15:38:15

Generated On: 11 Aug 2021 21:52:11

Date of study discontinuation/completion (dd MMM yyyy)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3032201

Folder: SAE USA-US032-2021-MRNA-1273-P301000009

Form: Safety Report Form

Data signed: (b) (4) 22 Feb 2021 17:25:31

Generated On: 11 Aug 2021 21:52:11

SAEID	USA-US032-2021-MRNA-1273-P301000009
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3032201

Folder: SAE USA-US032-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) 22 Feb 2021 17:25:31

Generated On: 11 Aug 2021 21:52:11

SAEID	USA-US032-2021-MRNA-1273-P301000009
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	19/FEB/2021 12:47
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3032201 (Prod: Meridian Clinical Research (Norfolk-Nebraska))

US3032201

Form: Participant Creation

Generated On: 11 Aug 2021 21:52:11

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:55:00
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'US3032201'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 22:49:07

US3032201

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:52:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	13 Aug 2020 13:44:59

US3032201

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '12 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 22:49:08

US3032201

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:52:11

[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 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Clinic (Clinic)'	Kelsey Kelley (b) (4)	13 Aug 2020 13:44:59

US3032201

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:52:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered 'SCRN'	System	13 Aug 2020 13:44:59

US3032201

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:11

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered (b) (6) 1982'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 22:49:09

US3032201

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:11

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '38'	Kelsey Kelley (b) (4)	13 Aug 2020 13:46:57

US3032201

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:11

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered 'YEARS'	System	13 Aug 2020 13:46:57

US3032201

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:11

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered '38'	System	12 Aug 2020 23:47:05

US3032201

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:11

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Female (F)'	Kelsey Kelley (b) (4)	13 Aug 2020 13:46:57

US3032201

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:11

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Kelsey Kelley (b) (4)	13 Aug 2020 13:46:57

US3032201

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:11

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'I'	Kelsey Kelley (b) (4)	13 Aug 2020 13:46:57

US3032201

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:11

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '0'	Kelsey Kelley (b) (4)	13 Aug 2020 13:46:57

US3032201

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:11

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '0'	Kelsey Kelley (b) (4)	13 Aug 2020 13:46:57

US3032201

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:11

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '0'	Kelsey Kelley (b) (4)	13 Aug 2020 13:46:57

US3032201

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:11

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '0'	Kelsey Kelley (b) (4)	13 Aug 2020 13:46:57

US3032201

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:11

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '0'	Kelsey Kelley (b) (4)	13 Aug 2020 13:46:57

US3032201

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:11

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered empty.	Kelsey Kelley (b) (4)	13 Aug 2020 13:46:57

US3032201

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:11

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '0'	Kelsey Kelley (b) (4)	13 Aug 2020 13:46:57

US3032201

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:11

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '0'	Kelsey Kelley (b) (4)	13 Aug 2020 13:46:57

US3032201

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:52:11

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '12 Aug 2020'	Kelsey Kelley (b) (4)	12 Aug 2020 23:47:05

US3032201

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered 'Aug 2020'	System	12 Aug 2020 23:47:05

US3032201

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered '2020'	System	12 Aug 2020 23:47:05

US3032201

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:52:11

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Amendment 2 (2)'	Kelsey Kelley (b) (4)	12 Aug 2020 23:47:05

US3032201

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	12 Aug 2020 23:47:05

US3032201

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered empty.	Kelsey Kelley (b) (4)	12 Aug 2020 23:47:05

US3032201

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:52:11

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered empty.	Kelsey Kelley (b) (4)	12 Aug 2020 23:47:05

US3032201

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:52:11

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	12 Aug 2020 23:47:05

US3032201

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:52:11

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 22:49:08

US3032201

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:52:11

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered 'I'	System	12 Aug 2020 23:47:05

US3032201

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	12 Aug 2020 23:46:56

US3032201

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 21:52:11

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	13 Aug 2020 13:51:18

US3032201

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:52:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 09:35:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 09:35:32
Data point term sent to Coder	System	13 Aug 2020 13:52:03
User entered 'seasonal allergies-no medication taken'	Kelsey Kelley (b) (4)	13 Aug 2020 13:51:42

US3032201

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'un UNK 1990'	Kelsey Kelley (b) (4)	13 Aug 2020 13:51:42

US3032201

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:52:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '0'	Kelsey Kelley (b) (4)	13 Aug 2020 13:51:42

US3032201

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:52:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	13 Aug 2020 13:51:42

US3032201

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered empty.	Kelsey Kelley (b) (4)	13 Aug 2020 13:51:42

US3032201

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:52:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '0'	Kelsey Kelley (b) (4)	13 Aug 2020 13:51:42

US3032201

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered 'Jan 1990'	System	13 Aug 2020 13:51:42

US3032201

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered '1990'	System	13 Aug 2020 13:51:42

US3032201

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered empty.	System	13 Aug 2020 13:51:42

US3032201

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered empty.	System	13 Aug 2020 13:51:42

US3032201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	13 Aug 2020 13:51:05

US3032201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '12 Aug 2020'	Kelsey Kelley (b) (4)	13 Aug 2020 13:51:05

US3032201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '17:45'	Kelsey Kelley (b) (4)	13 Aug 2020 13:51:05

US3032201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered '12 Aug 2020 17:45'	System	13 Aug 2020 13:51:05

US3032201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '172.7' cm	(b) (4) Kelsey Kelley (b) (4)	13 Aug 2020 13:51:05
DataPoint set to visible.	(b) (4) System	12 Aug 2020 23:47:05

US3032201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '92.0' kg	(b) (4) Kelsey Kelley (b) (4)	13 Aug 2020 13:51:05
DataPoint set to visible.	(b) (4) System	12 Aug 2020 23:47:05

US3032201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
Amendment Manager: User entered '30.84631'	System	16 Sep 2020 23:54:36
User entered '30.8'	System	13 Aug 2020 13:51:05
DataPoint set to visible.	System	12 Aug 2020 23:47:05

US3032201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered 'kg/m2'	System	13 Aug 2020 13:51:05
DataPoint set to visible.	System	12 Aug 2020 23:47:05

US3032201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:35:45
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 06:52:22
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' answered with 'DATA UPDATED' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 14:35:13
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 14:35:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 14:35:06
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 11:32:52
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:33:30
User entered '36.7' C	Kelsey Kelley (b) (4) (b) (4)	13 Aug 2020 13:51:05

US3032201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:35:45
Signature has been broken.	Linden DeBoer (b) (4)	07 Oct 2020 14:35:06
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4)	07 Oct 2020 14:35:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Oral (Oral)'	Kelsey Kelley (b) (4)	13 Aug 2020 13:51:05

US3032201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered empty.	Kelsey Kelley (b) (4)	13 Aug 2020 13:51:05

US3032201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:35:45
Signature has been broken.	Linden DeBoer (b) (4)	07 Oct 2020 14:35:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	07 Oct 2020 14:35:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '82'	Kelsey Kelley (b) (4)	13 Aug 2020 13:51:05

US3032201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered 'bpm'	System	13 Aug 2020 13:51:05

US3032201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:35:45
Signature has been broken.	Linden DeBoer (b) (4)	07 Oct 2020 14:35:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	07 Oct 2020 14:35:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '16'	Kelsey Kelley (b) (4)	13 Aug 2020 13:51:05

US3032201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered 'breaths/min'	System	13 Aug 2020 13:51:05

US3032201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:35:45
Signature has been broken.	Linden DeBoer (b) (4)	07 Oct 2020 14:35:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	07 Oct 2020 14:35:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '124'	Kelsey Kelley (b) (4)	13 Aug 2020 13:51:05

US3032201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered 'mmHg'	System	13 Aug 2020 13:51:05

US3032201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:35:45
Signature has been broken.	Linden DeBoer (b) (4)	07 Oct 2020 14:35:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	07 Oct 2020 14:35:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '85'	Kelsey Kelley (b) (4)	13 Aug 2020 13:51:05

US3032201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered 'mmHg'	System	13 Aug 2020 13:51:05

US3032201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02

US3032201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02

US3032201

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	13 Aug 2020 13:48:09

US3032201

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
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)	11 Sep 2020 12:44:37
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	10 Sep 2020 20:55:59
User closed query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	13 Aug 2020 13:48:21
Query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	13 Aug 2020 13:48:21
User entered '12 Aug 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	13 Aug 2020 13:48:21
User opened query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	13 Aug 2020 13:48:09
User entered '13 Aug 2020'	Kelsey Kelley (b) (4) (b) (4)	13 Aug 2020 13:48:09

US3032201

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:52:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '12 Aug 2020'	Kelsey Kelley (b) (4)	13 Aug 2020 13:48:32

US3032201

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	13 Aug 2020 13:48:32

US3032201

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered empty.	Kelsey Kelley (b) (4)	13 Aug 2020 13:48:32

US3032201

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:52:11

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered empty.	Kelsey Kelley (b) (4)	13 Aug 2020 13:48:32

US3032201

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered empty.	Kelsey Kelley (b) (4)	13 Aug 2020 13:48:32

US3032201

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:52:11

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '0'	Kelsey Kelley (b) (4)	13 Aug 2020 13:48:32

US3032201

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered empty.	Kelsey Kelley (b) (4)	13 Aug 2020 13:48:32

US3032201

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:52:11

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '0'	Kelsey Kelley (b) (4)	13 Aug 2020 13:48:32

US3032201

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	13 Aug 2020 13:52:00

US3032201

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User closed query 'Pregnancy Test is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	(b) (4)	13 Aug 2020 13:52:14
Query 'Pregnancy Test is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	13 Aug 2020 13:52:14
User entered '12 Aug 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	13 Aug 2020 13:52:14
User opened query 'Pregnancy Test is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	(b) (4)	13 Aug 2020 13:52:00
User entered '13 Aug 2020'	System	13 Aug 2020 13:52:00
	Kelsey Kelley (b) (4)	13 Aug 2020 13:52:00
	(b) (4)	

US3032201

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Urine (URINE)'	Kelsey Kelley (b) (4)	13 Aug 2020 13:52:00

US3032201

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Negative (NEGATIVE)'	Kelsey Kelley (b) (4)	13 Aug 2020 13:52:00

US3032201

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'No (N)'	Kelsey Kelley (b) (4)	13 Aug 2020 13:52:00

US3032201

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered empty.	Kelsey Kelley (b) (4)	13 Aug 2020 13:52:00

US3032201

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered empty.	Kelsey Kelley (b) (4)	13 Aug 2020 13:52:00

US3032201

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered empty.	System	13 Aug 2020 13:52:00

US3032201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:11

[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 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	13 Aug 2020 13:47:31

US3032201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:11

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 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'No (N)'	Kelsey Kelley (b) (4)	13 Aug 2020 13:47:31

US3032201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:11

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 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'No (N)'	Kelsey Kelley (b) (4)	13 Aug 2020 13:47:31

US3032201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:11

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 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	13 Aug 2020 13:47:31

US3032201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:11

[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 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'No (N)'	Kelsey Kelley (b) (4)	13 Aug 2020 13:47:31

US3032201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:11

[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 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'No (N)'	Kelsey Kelley (b) (4)	13 Aug 2020 13:47:31

US3032201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:11

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 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'No (N)'	Kelsey Kelley (b) (4)	13 Aug 2020 13:47:31

US3032201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:11

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 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'No (N)'	Kelsey Kelley (b) (4)	13 Aug 2020 13:47:31

US3032201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:11

[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 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'No (N)'	Kelsey Kelley (b) (4)	13 Aug 2020 13:47:31

US3032201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:11

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 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'No (N)'	Kelsey Kelley (b) (4)	13 Aug 2020 13:47:31

US3032201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:11

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 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'No (N)'	Kelsey Kelley (b) (4)	13 Aug 2020 13:47:31

US3032201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:11

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	13 Aug 2020 13:47:31
	(b) (4)	

US3032201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:11

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered empty.	Kelsey Kelley (b) (4)	13 Aug 2020 13:47:31

US3032201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:11

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'I'	Kelsey Kelley (b) (4)	13 Aug 2020 13:47:31

US3032201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '0'	Kelsey Kelley (b) (4)	13 Aug 2020 13:47:31

US3032201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:11

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 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '0'	Kelsey Kelley (b) (4)	13 Aug 2020 13:47:31

US3032201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:11

[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 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '0'	Kelsey Kelley (b) (4)	13 Aug 2020 13:47:31

US3032201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:11

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 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '0'	Kelsey Kelley (b) (4)	13 Aug 2020 13:47:31

US3032201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '0'	Kelsey Kelley (b) (4)	13 Aug 2020 13:47:31

US3032201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:11

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '0'	Kelsey Kelley (b) (4)	13 Aug 2020 13:47:31

US3032201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:11

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered empty.	Kelsey Kelley (b) (4)	13 Aug 2020 13:47:31

US3032201

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:52:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	13 Aug 2020 13:46:31

US3032201

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '12 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	13 Aug 2020 13:46:31

US3032201

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Clinic (Clinic)'	Kelsey Kelley (b) (4)	13 Aug 2020 13:46:31

US3032201

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:52:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered 'VISIT1'	System	13 Aug 2020 13:46:31

US3032201

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '12 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 23:24:11

US3032201

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 04:03:23
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:03:23
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Aug 2020 23:24:11
User entered '103573' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 23:24:11

US3032201

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 23:24:11

US3032201

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:52:11

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)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	13 Aug 2020 13:46:22

US3032201

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:52:11

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)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'No (N)'	Kelsey Kelley (b) (4)	13 Aug 2020 13:46:22

US3032201

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	13 Aug 2020 13:46:22

US3032201

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	13 Aug 2020 13:46:22

US3032201

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:52:11

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	13 Aug 2020 13:46:22

US3032201

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:52:11

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	02 Nov 2020 22:10:16
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Nov 2020 07:44:19
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	29 Oct 2020 17:07:32
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	29 Oct 2020 17:07:27
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 11:21:20
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:19:16
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:55:33

US3032201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:11

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:55:13
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 04:52:22
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' answered with 'DATA UPDATED' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	12 Oct 2020 12:22:58
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	12 Oct 2020 12:22:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	12 Oct 2020 12:22:54
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 11:53:56
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:33:30
User entered '172.7' cm	Kelsey Kelley (b) (4) (b) (4)	13 Aug 2020 13:49:32

US3032201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:55:13
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	12 Oct 2020 12:22:54
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	12 Oct 2020 12:22:54
User signature succeeded.	(b) (4)	
	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
	(b) (4)	
User entered '92.0' kg	Kelsey Kelley (b) (4)	13 Aug 2020 13:49:32
	(b) (4)	

US3032201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:11

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:55:13
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 04:52:22
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' answered with 'DATA UPDATED' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	12 Oct 2020 12:22:58
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	12 Oct 2020 12:22:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	12 Oct 2020 12:22:54
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 11:53:56
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:33:30
User entered '172.7' cm	Kelsey Kelley (b) (4) (b) (4)	13 Aug 2020 13:49:32

US3032201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:55:13
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	12 Oct 2020 12:22:54
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	12 Oct 2020 12:22:54
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
	(b) (4)	
User entered '92.0' kg	Kelsey Kelley (b) (4)	13 Aug 2020 13:49:32
	(b) (4)	

US3032201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	13 Aug 2020 13:49:32

US3032201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	13 Aug 2020 13:49:32
	(b) (4)	

US3032201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '12 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	13 Aug 2020 13:49:32
	(b) (4)	

US3032201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '17:45'	(b) (4) Kelsey Kelley (b) (4)	13 Aug 2020 13:49:32

US3032201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered '12 Aug 2020 17:45'	System	13 Aug 2020 13:49:32

US3032201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '36.7' C	Kelsey Kelley (b) (4)	13 Aug 2020 13:49:32

US3032201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	13 Aug 2020 13:49:32
	(b) (4)	

US3032201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	13 Aug 2020 13:49:32
	(b) (4)	

US3032201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '82'	(b) (4) Kelsey Kelley (b) (4)	13 Aug 2020 13:49:32

US3032201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered 'bpm'	System	13 Aug 2020 13:49:32

US3032201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '16'	(b) (4) Kelsey Kelley (b) (4)	13 Aug 2020 13:49:32

US3032201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered 'breaths/min'	System	13 Aug 2020 13:49:32

US3032201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '124'	(b) (4) Kelsey Kelley (b) (4)	13 Aug 2020 13:49:32

US3032201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered 'mmHg'	System	13 Aug 2020 13:49:32

US3032201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '85'	(b) (4) Kelsey Kelley (b) (4)	13 Aug 2020 13:49:32

US3032201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered 'mmHg'	System	13 Aug 2020 13:49:32

US3032201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:11

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:55:13
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 04:52:22
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' answered with 'DATA UPDATED' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	12 Oct 2020 12:22:58
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	12 Oct 2020 12:22:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	12 Oct 2020 12:22:54
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 11:53:56
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:33:30
User entered '172.7' cm	Kelsey Kelley (b) (4) (b) (4)	13 Aug 2020 13:49:32

US3032201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:55:13
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	12 Oct 2020 12:22:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	12 Oct 2020 12:22:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '92.0' kg	(b) (4)	
	Kelsey Kelley (b) (4)	13 Aug 2020 13:49:32
	(b) (4)	

US3032201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	13 Aug 2020 13:50:19

US3032201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	13 Aug 2020 13:50:19
	(b) (4)	

US3032201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '12 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	13 Aug 2020 13:50:19
	(b) (4)	

US3032201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
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).	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:27:24
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 MIN per protocol' (Site from System).	Kelsey Kelley (b) (4) (b) (4)	13 Aug 2020 13:50:28
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).		13 Aug 2020 13:50:19
User entered '19:19'	Kelsey Kelley (b) (4) (b) (4)	13 Aug 2020 13:50:19

US3032201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered '12 Aug 2020 19:19'	System	13 Aug 2020 13:50:19

US3032201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '36.7' C	Kelsey Kelley (b) (4)	13 Aug 2020 13:50:19

US3032201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	13 Aug 2020 13:50:19
	(b) (4)	

US3032201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	13 Aug 2020 13:50:19
	(b) (4)	

US3032201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '79'	(b) (4) Kelsey Kelley (b) (4)	13 Aug 2020 13:50:19

US3032201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered 'bpm'	System	13 Aug 2020 13:50:19

US3032201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '16'	(b) (4) Kelsey Kelley (b) (4)	13 Aug 2020 13:50:19

US3032201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered 'breaths/min'	System	13 Aug 2020 13:50:19

US3032201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '116'	(b) (4) Kelsey Kelley (b) (4)	13 Aug 2020 13:50:19

US3032201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered 'mmHg'	System	13 Aug 2020 13:50:19

US3032201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '84'	(b) (4) Kelsey Kelley (b) (4)	13 Aug 2020 13:50:19

US3032201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered 'mmHg'	System	13 Aug 2020 13:50:19

US3032201

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	13 Aug 2020 13:52:41

US3032201

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	13 Aug 2020 13:52:47
User entered '12 Aug 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	13 Aug 2020 13:52:47
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	13 Aug 2020 13:52:41
User entered '13 Aug 2020'	Kelsey Kelley (b) (4)	13 Aug 2020 13:52:41

US3032201

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 16:37:26
User closed query 'Per CDM: Per CCGs, when Screening and Visit 1 Day 1 occur on the same day 'Was the pregnancy test performed?' and "Was FSH sample collected?" should be marked as "No" at Visit 1 Day 1 and pregnancy test data should not be recorded on this page. Please review and update Pregnancy test form at Visit 1 Day 1 as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 08:10:40
Query 'Per CDM: Per CCGs, when Screening and Visit 1 Day 1 occur on the same day 'Was the pregnancy test performed?' and "Was FSH sample collected?" should be marked as "No" at Visit 1 Day 1 and pregnancy test data should not be recorded on this page. Please review and update Pregnancy test form at Visit 1 Day 1 as appropriate. ' answered with 'data updated' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	23 Oct 2020 17:06:15
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	23 Oct 2020 17:06:04
User entered 'No (N)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	23 Oct 2020 17:06:04
User opened query 'Per CDM: Per CCGs, when Screening and Visit 1 Day 1 occur on the same day 'Was the pregnancy test performed?' and "Was FSH sample collected?" should be marked as "No" at Visit 1 Day 1 and pregnancy test data should not be recorded on this page. Please review and update Pregnancy test form at Visit 1 Day 1 as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:57:07
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:33:30
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	13 Aug 2020 13:52:26

US3032201

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 16:37:26
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	23 Oct 2020 17:06:04
User entered empty; reason for change Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	23 Oct 2020 17:06:04
User signature succeeded.	(b) (4)	
	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User closed query 'Date of Test is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	
	System	13 Aug 2020 13:52:32
Query 'Date of Test is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	13 Aug 2020 13:52:32
User entered '12 Aug 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	13 Aug 2020 13:52:32
	(b) (4)	
User opened query 'Date of Test is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	13 Aug 2020 13:52:26
User entered '13 Aug 2020'	Kelsey Kelley (b) (4)	13 Aug 2020 13:52:26
	(b) (4)	

US3032201

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 16:37:26
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	23 Oct 2020 17:06:04
	(b) (4)	
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4)	23 Oct 2020 17:06:04
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
	(b) (4)	
User entered 'Urine (URINE)'	Kelsey Kelley (b) (4)	13 Aug 2020 13:52:26
	(b) (4)	

US3032201

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 16:37:26
Signature has been broken.	Linden DeBoer (b) (4)	23 Oct 2020 17:06:04
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4)	23 Oct 2020 17:06:04
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Negative (NEGATIVE)'	Kelsey Kelley (b) (4)	13 Aug 2020 13:52:26

US3032201

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 16:37:26
User closed query 'Per CDM: Per CCGs, "Was FSH sample collected?" question is to be answered and the field should not remain empty. Please update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 10:01:48
Query 'Per CDM: Per CCGs, "Was FSH sample collected?" question is to be answered and the field should not remain empty. Please update as appropriate.' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	27 Oct 2020 13:20:24
User entered 'No (N)' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	27 Oct 2020 13:20:18
User opened query 'Per CDM: Per CCGs, "Was FSH sample collected?" question is to be answered and the field should not remain empty. Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 08:10:44
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	23 Oct 2020 17:06:04
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	23 Oct 2020 17:06:04
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:33:30
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	13 Aug 2020 13:52:26

US3032201

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	13 Aug 2020 13:52:26

US3032201

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	13 Aug 2020 13:52:26

US3032201

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered empty.	System	13 Aug 2020 13:52:26

US3032201

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	12 Aug 2020 23:47:21

US3032201

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	12 Aug 2020 23:47:21
	(b) (4)	

US3032201

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	12 Aug 2020 23:47:21

US3032201

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered 'MRNA-1273 OR PLACEBO'	System	12 Aug 2020 23:47:21

US3032201

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '12 Aug 2020'	Kelsey Kelley (b) (4)	12 Aug 2020 23:47:21

US3032201

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '18:43'	Kelsey Kelley (b) (4)	12 Aug 2020 23:47:21

US3032201

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered '12 Aug 2020 18:43'	System	12 Aug 2020 23:47:21

US3032201

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Left Arm (LEFT ARM)'	Kelsey Kelley (b) (4)	12 Aug 2020 23:47:21

US3032201

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered 'ONCE'	System	12 Aug 2020 23:47:21

US3032201

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered 'INTRAMUSCULAR'	System	12 Aug 2020 23:47:21

US3032201

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	13 Aug 2020 13:53:02

US3032201

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '12 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	13 Aug 2020 13:53:02
	(b) (4)	

US3032201

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '18:18'	(b) (4) Kelsey Kelley (b) (4)	13 Aug 2020 13:53:02

US3032201

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered '12 Aug 2020 18:18'	System	13 Aug 2020 13:53:02

US3032201

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 21:52:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '12 Aug 2020'	Kelsey Kelley (b) (4)	13 Aug 2020 13:53:19

US3032201

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:52:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kelsey Kelley (b) (4) (b) (4)	13 Aug 2020 13:53:19

US3032201

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:52:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	13 Aug 2020 13:53:19

US3032201

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:52:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '16:01'	(b) (4) Kelsey Kelley (b) (4)	13 Aug 2020 13:53:19

US3032201

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered '12 Aug 2020 16:01'	System	13 Aug 2020 13:53:19

US3032201

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:52:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kelsey Kelley (b) (4) (b) (4)	13 Aug 2020 13:53:19

US3032201

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:52:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	13 Aug 2020 13:53:19

US3032201

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:52:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered empty.	Kelsey Kelley (b) (4)	13 Aug 2020 13:53:19

US3032201

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered empty.	System	13 Aug 2020 13:53:19

US3032201

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	13 Aug 2020 13:53:49

US3032201

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered 'I'	System	13 Aug 2020 13:53:49

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-12T19:10:55', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '5eb58c88-924d-432a-8d84-2e322c58f5e7'	System	13 Aug 2020 00:11:27
User entered 'Yes (Y)'	System	13 Aug 2020 00:11:27

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-12T19:11:01', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '5eb58c88-924d-432a-8d84-2e322c58f5e7' User entered '98.0'	System	13 Aug 2020 00:11:27

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-12T19:11:05', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '5eb58c88-924d-432a-8d84-2e322c58f5e7'	System	13 Aug 2020 00:11:27
User entered 'No (N)'	System	13 Aug 2020 00:11:27

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-12T19:11:16', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '5eb58c88-924d-432a-8d84-2e322c58f5e7'	System	13 Aug 2020 00:11:27
User entered '12 Aug 2020 19:11'	System	13 Aug 2020 00:11:27

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '12 Aug 2020 19:03'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '12 Aug 2020 21:33'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '12 Aug 2020 22:28'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered 'Day 2'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:52:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-13T19:00:14', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'ade80362-408d-41a8-bb37-cc4dfc9489c4'	System	14 Aug 2020 00:00:48
User entered 'Yes (Y)'	System	14 Aug 2020 00:00:48

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:52:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-13T19:00:24', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'ade80362-408d-41a8-bb37-cc4dfc9489c4'	System	14 Aug 2020 00:00:48
User entered '97.2'	System	14 Aug 2020 00:00:48

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-13T19:00:34', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'ade80362-408d-41a8-bb37-cc4dfc9489c4'	System	14 Aug 2020 00:00:48
User entered 'No (N)'	System	14 Aug 2020 00:00:48

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:52:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-13T19:00:42', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'ade80362-408d-41a8-bb37-cc4dfc9489c4'	System	14 Aug 2020 00:00:48
User entered '13 Aug 2020 19:00'	System	14 Aug 2020 00:00:48

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered 'Day 3'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:52:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-14T20:45:10', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'b1377529-17eb-4c52-a6f4-b2bc86c09c9d'	System	15 Aug 2020 01:46:34
User entered 'Yes (Y)'	System	15 Aug 2020 01:46:34

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:52:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-14T20:46:12', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'b1377529-17eb-4c52-a6f4-b2bc86c09c9d'	System	15 Aug 2020 01:46:34
User entered '96.6'	System	15 Aug 2020 01:46:34

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-14T20:46:17', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'b1377529-17eb-4c52-a6f4-b2bc86c09c9d'	System	15 Aug 2020 01:46:34
User entered 'No (N)'	System	15 Aug 2020 01:46:34

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:52:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-14T20:46:26', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'b1377529-17eb-4c52-a6f4-b2bc86c09c9d'	System	15 Aug 2020 01:46:34
User entered '14 Aug 2020 20:46'	System	15 Aug 2020 01:46:34

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered 'Day 4'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:52:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-15T21:51:48', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'c9de8239-06fa-4f01-8d62-bb90e4d16861'	System	16 Aug 2020 02:52:24
User entered 'Yes (Y)'	System	16 Aug 2020 02:52:24

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:52:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-15T21:51:56', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'c9de8239-06fa-4f01-8d62-bb90e4d16861'	System	16 Aug 2020 02:52:24
User entered '97.2'	System	16 Aug 2020 02:52:24

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-15T21:52:01', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'c9de8239-06fa-4f01-8d62-bb90e4d16861'	System	16 Aug 2020 02:52:24
User entered 'No (N)'	System	16 Aug 2020 02:52:24

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:52:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-15T21:52:13', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'c9de8239-06fa-4f01-8d62-bb90e4d16861'	System	16 Aug 2020 02:52:24
User entered '15 Aug 2020 21:52'	System	16 Aug 2020 02:52:24

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered 'Day 5'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:52:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-16T19:57:34', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '9db9605d-ab13-45f8-a235-855b39072c09'	System	17 Aug 2020 00:58:05
User entered 'Yes (Y)'	System	17 Aug 2020 00:58:05

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:52:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-16T19:57:45', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '9db9605d-ab13-45f8-a235-855b39072c09'	System	17 Aug 2020 00:58:05
User entered '97.4'	System	17 Aug 2020 00:58:05

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-16T19:57:51', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '9db9605d-ab13-45f8-a235-855b39072c09'	System	17 Aug 2020 00:58:05
User entered 'No (N)'	System	17 Aug 2020 00:58:05

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:52:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-16T19:57:59', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '9db9605d-ab13-45f8-a235-855b39072c09'	System	17 Aug 2020 00:58:05
User entered '16 Aug 2020 19:57'	System	17 Aug 2020 00:58:05

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered 'Day 6'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:52:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-17T21:05:37', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'db3be54a-635e-4b6d-bf0f-10019ce9cfef'	System	18 Aug 2020 02:05:58
User entered 'Yes (Y)'	System	18 Aug 2020 02:05:58

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:52:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-17T21:05:42', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'db3be54a-635e-4b6d-bf0f-10019ce9cfef'	System	18 Aug 2020 02:05:58
User entered '97.8'	System	18 Aug 2020 02:05:58

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-17T21:05:47', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'db3be54a-635e-4b6d-bf0f-10019ce9cfef'	System	18 Aug 2020 02:05:58
User entered 'No (N)'	System	18 Aug 2020 02:05:58

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:52:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-17T21:05:53', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'db3be54a-635e-4b6d-bf0f-10019ce9cfef'	System	18 Aug 2020 02:05:58
User entered '17 Aug 2020 21:05'	System	18 Aug 2020 02:05:58

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered 'Day 7'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:52:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-18T19:52:42', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '439cf1b8-3e63-4464-a704-f58e009e5e01'	System	19 Aug 2020 00:53:09
User entered 'Yes (Y)'	System	19 Aug 2020 00:53:09

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:52:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-18T19:52:50', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '439cf1b8-3e63-4464-a704-f58e009e5e01'	System	19 Aug 2020 00:53:09
User entered '97.4'	System	19 Aug 2020 00:53:09

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-18T19:52:53', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '439cf1b8-3e63-4464-a704-f58e009e5e01'	System	19 Aug 2020 00:53:09
User entered 'No (N)'	System	19 Aug 2020 00:53:09

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:52:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-18T19:53:02', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '439cf1b8-3e63-4464-a704-f58e009e5e01'	System	19 Aug 2020 00:53:09
User entered '18 Aug 2020 19:53'	System	19 Aug 2020 00:53:09

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-12T19:11:45', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '8ae3a25c-eb6c-4231-99cb-8e1a1b02fa72'	System	13 Aug 2020 00:12:06
User entered 'None (1)'	System	13 Aug 2020 00:12:06

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-12T19:11:47', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '8ae3a25c-eb6c-4231-99cb-8e1a1b02fa72'	System	13 Aug 2020 00:12:06
User entered 'No (N)'	System	13 Aug 2020 00:12:06

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-12T19:11:49', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '8ae3a25c-eb6c-4231-99cb-8e1a1b02fa72'	System	13 Aug 2020 00:12:06
User entered 'No (N)'	System	13 Aug 2020 00:12:06

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-12T19:11:54', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '8ae3a25c-eb6c-4231-99cb-8e1a1b02fa72'	System	13 Aug 2020 00:12:06
User entered 'None (1)'	System	13 Aug 2020 00:12:06

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-12T19:11:57', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '8ae3a25c-eb6c-4231-99cb-8e1a1b02fa72'	System	13 Aug 2020 00:12:06
User entered '12 Aug 2020 19:11'	System	13 Aug 2020 00:12:06

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '12 Aug 2020 19:03'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '12 Aug 2020 21:33'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '12 Aug 2020 22:28'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered 'Day 2'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:52:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-13T18:57:07', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '08ce0eea-16fd-4c5b-82e3-ac7806836115'	System	13 Aug 2020 23:58:21
User entered 'None (1)'	System	13 Aug 2020 23:58:21

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-13T18:57:37', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '08ce0eea-16fd-4c5b-82e3-ac7806836115'	System	13 Aug 2020 23:58:21
User entered 'No (N)'	System	13 Aug 2020 23:58:21

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-13T18:57:51', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '08ce0eea-16fd-4c5b-82e3-ac7806836115'	System	13 Aug 2020 23:58:21
User entered 'No (N)'	System	13 Aug 2020 23:58:21

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:52:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-13T18:58:02', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '08ce0eea-16fd-4c5b-82e3-ac7806836115'	System	13 Aug 2020 23:58:21
User entered 'None (1)'	System	13 Aug 2020 23:58:21

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:52:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-13T18:58:17', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '08ce0eea-16fd-4c5b-82e3-ac7806836115'	System	13 Aug 2020 23:58:21
User entered '13 Aug 2020 18:58'	System	13 Aug 2020 23:58:21

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered 'Day 3'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:52:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-14T20:46:47', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '590c926b-979b-44d8-871f-416ac4c1db04'	System	15 Aug 2020 01:47:18
User entered 'None (1)'	System	15 Aug 2020 01:47:18

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:52:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-14T20:46:49', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '590c926b-979b-44d8-871f-416ac4c1db04'	System	15 Aug 2020 01:47:18
User entered 'No (N)'	System	15 Aug 2020 01:47:18

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-14T20:46:52', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '590c926b-979b-44d8-871f-416ac4c1db04'	System	15 Aug 2020 01:47:18
User entered 'No (N)'	System	15 Aug 2020 01:47:18

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:52:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-14T20:47:01', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '590c926b-979b-44d8-871f-416ac4c1db04'	System	15 Aug 2020 01:47:18
User entered 'None (1)'	System	15 Aug 2020 01:47:18

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:52:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-14T20:47:12', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '590c926b-979b-44d8-871f-416ac4c1db04'	System	15 Aug 2020 01:47:18
User entered '14 Aug 2020 20:47'	System	15 Aug 2020 01:47:18

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered 'Day 4'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:52:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-15T21:52:17', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '019c1ef3-6cb7-47de-a2b6-578ce13f1f79'	System	16 Aug 2020 02:52:47
User entered 'None (1)'	System	16 Aug 2020 02:52:47

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:52:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-15T21:52:21', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '019c1ef3-6cb7-47de-a2b6-578ce13f1f79'	System	16 Aug 2020 02:52:47
User entered 'No (N)'	System	16 Aug 2020 02:52:47

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-15T21:52:24', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '019c1ef3-6cb7-47de-a2b6-578ce13f1f79'	System	16 Aug 2020 02:52:47
User entered 'No (N)'	System	16 Aug 2020 02:52:47

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:52:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-15T21:52:27', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '019c1ef3-6cb7-47de-a2b6-578ce13f1f79'	System	16 Aug 2020 02:52:47
User entered 'None (1)'	System	16 Aug 2020 02:52:47

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:52:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-15T21:52:37', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '019c1ef3-6cb7-47de-a2b6-578ce13f1f79'	System	16 Aug 2020 02:52:47
User entered '15 Aug 2020 21:52'	System	16 Aug 2020 02:52:47

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered 'Day 5'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:52:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-16T19:56:30', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '8f52f33a-f088-44eb-aa13-243e50be03cd'	System	17 Aug 2020 00:56:59
User entered 'None (1)'	System	17 Aug 2020 00:56:59

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:52:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-16T19:56:34', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '8f52f33a-f088-44eb-aa13-243e50be03cd'	System	17 Aug 2020 00:56:59
User entered 'No (N)'	System	17 Aug 2020 00:56:59

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-16T19:56:36', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '8f52f33a-f088-44eb-aa13-243e50be03cd'	System	17 Aug 2020 00:56:59
User entered 'No (N)'	System	17 Aug 2020 00:56:59

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:52:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-16T19:56:39', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '8f52f33a-f088-44eb-aa13-243e50be03cd'	System	17 Aug 2020 00:56:59
User entered 'None (1)'	System	17 Aug 2020 00:56:59

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:52:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-16T19:56:56', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '8f52f33a-f088-44eb-aa13-243e50be03cd'	System	17 Aug 2020 00:56:59
User entered '16 Aug 2020 19:56'	System	17 Aug 2020 00:56:59

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered 'Day 6'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:52:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-17T21:05:09', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '6d6ebda9-e24d-42f1-94e3-3ab2b5e8c20c'	System	18 Aug 2020 02:05:32
User entered 'None (1)'	System	18 Aug 2020 02:05:32

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-17T21:05:12', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '6d6ebda9-e24d-42f1-94e3-3ab2b5e8c20c'	System	18 Aug 2020 02:05:32
User entered 'No (N)'	System	18 Aug 2020 02:05:32

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-17T21:05:14', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '6d6ebda9-e24d-42f1-94e3-3ab2b5e8c20c'	System	18 Aug 2020 02:05:32
User entered 'No (N)'	System	18 Aug 2020 02:05:32

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:52:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-17T21:05:20', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '6d6ebda9-e24d-42f1-94e3-3ab2b5e8c20c'	System	18 Aug 2020 02:05:32
User entered 'None (1)'	System	18 Aug 2020 02:05:32

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:52:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-17T21:05:27', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '6d6ebda9-e24d-42f1-94e3-3ab2b5e8c20c'	System	18 Aug 2020 02:05:32
User entered '17 Aug 2020 21:05'	System	18 Aug 2020 02:05:32

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered 'Day 7'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:52:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-18T19:51:51', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'aafac8b0-5d1c-4509-983d-e9d0cd5607a7'	System	19 Aug 2020 00:52:38
User entered 'None (1)'	System	19 Aug 2020 00:52:38

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:52:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-18T19:52:00', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'aafac8b0-5d1c-4509-983d-e9d0cd5607a7'	System	19 Aug 2020 00:52:38
User entered 'No (N)'	System	19 Aug 2020 00:52:38

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-18T19:52:03', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'aafac8b0-5d1c-4509-983d-e9d0cd5607a7'	System	19 Aug 2020 00:52:38
User entered 'No (N)'	System	19 Aug 2020 00:52:38

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:52:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-18T19:52:17', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'aafac8b0-5d1c-4509-983d-e9d0cd5607a7'	System	19 Aug 2020 00:52:38
User entered 'None (1)'	System	19 Aug 2020 00:52:38

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:52:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-18T19:52:33', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'aafac8b0-5d1c-4509-983d-e9d0cd5607a7'	System	19 Aug 2020 00:52:38
User entered '18 Aug 2020 19:52'	System	19 Aug 2020 00:52:38

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-12T19:12:04', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '4cad5ccb-8b32-4928-baec-8516dc2ae7e4'	System	13 Aug 2020 00:12:47
User entered 'None (0)'	System	13 Aug 2020 00:12:47

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-12T19:12:18', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '4cad5ccb-8b32-4928-baec-8516dc2ae7e4'	System	13 Aug 2020 00:12:47
User entered 'None (0)'	System	13 Aug 2020 00:12:47

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-12T19:12:21', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '4cad5ccb-8b32-4928-baec-8516dc2ae7e4'	System	13 Aug 2020 00:12:47
User entered 'None (0)'	System	13 Aug 2020 00:12:47

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-12T19:12:25', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '4cad5ccb-8b32-4928-baec-8516dc2ae7e4'	System	13 Aug 2020 00:12:47
User entered 'None (0)'	System	13 Aug 2020 00:12:47

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-12T19:12:27', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '4cad5ccb-8b32-4928-baec-8516dc2ae7e4'	System	13 Aug 2020 00:12:47
User entered 'None (0)'	System	13 Aug 2020 00:12:47

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-12T19:12:30', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '4cad5ccb-8b32-4928-baec-8516dc2ae7e4'	System	13 Aug 2020 00:12:47
User entered 'None (0)'	System	13 Aug 2020 00:12:47

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

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)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-12T19:12:35', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '4cad5ccb-8b32-4928-baec-8516dc2ae7e4'	System	13 Aug 2020 00:12:47
User entered 'No (N)'	System	13 Aug 2020 00:12:47

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-12T19:12:38', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '4cad5ccb-8b32-4928-baec-8516dc2ae7e4'	System	13 Aug 2020 00:12:47
User entered '12 Aug 2020 19:12'	System	13 Aug 2020 00:12:47

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '12 Aug 2020 19:03'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '12 Aug 2020 21:33'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

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)	04 Mar 2021 22:51:13

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '12 Aug 2020 22:28'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered 'Day 2'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-13T18:58:21', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '2c1f224e-00b8-49cd-b06e-7f911cfa2c5f'	System	13 Aug 2020 23:58:54
User entered 'None (0)'	System	13 Aug 2020 23:58:54

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-13T18:58:24', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '2c1f224e-00b8-49cd-b06e-7f911cfa2c5f'	System	13 Aug 2020 23:58:54
User entered 'None (0)'	System	13 Aug 2020 23:58:54

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-13T18:58:26', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '2c1f224e-00b8-49cd-b06e-7f911cfa2c5f'	System	13 Aug 2020 23:58:54
User entered 'None (0)'	System	13 Aug 2020 23:58:54

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-13T18:58:29', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '2c1f224e-00b8-49cd-b06e-7f911cfa2c5f'	System	13 Aug 2020 23:58:54
User entered 'None (0)'	System	13 Aug 2020 23:58:54

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-13T18:58:31', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '2c1f224e-00b8-49cd-b06e-7f911cfa2c5f'	System	13 Aug 2020 23:58:54
User entered 'None (0)'	System	13 Aug 2020 23:58:54

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-13T18:58:33', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '2c1f224e-00b8-49cd-b06e-7f911cfa2c5f'	System	13 Aug 2020 23:58:54
User entered 'None (0)'	System	13 Aug 2020 23:58:54

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:11

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)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-13T18:58:39', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '2c1f224e-00b8-49cd-b06e-7f911cfa2c5f'	System	13 Aug 2020 23:58:54
User entered 'No (N)'	System	13 Aug 2020 23:58:54

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-13T18:58:49', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '2c1f224e-00b8-49cd-b06e-7f911cfa2c5f'	System	13 Aug 2020 23:58:54
User entered '13 Aug 2020 18:58'	System	13 Aug 2020 23:58:54

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered 'Day 3'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-14T20:47:17', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '33a2a852-83a2-483b-85aa-4f8391086634'	System	15 Aug 2020 01:47:43
User entered 'None (0)'	System	15 Aug 2020 01:47:43

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-14T20:47:19', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '33a2a852-83a2-483b-85aa-4f8391086634'	System	15 Aug 2020 01:47:43
User entered 'None (0)'	System	15 Aug 2020 01:47:43

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-14T20:47:22', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '33a2a852-83a2-483b-85aa-4f8391086634'	System	15 Aug 2020 01:47:43
User entered 'None (0)'	System	15 Aug 2020 01:47:43

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-14T20:47:25', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '33a2a852-83a2-483b-85aa-4f8391086634'	System	15 Aug 2020 01:47:43
User entered 'None (0)'	System	15 Aug 2020 01:47:43

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-14T20:47:27', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '33a2a852-83a2-483b-85aa-4f8391086634'	System	15 Aug 2020 01:47:43
User entered 'None (0)'	System	15 Aug 2020 01:47:43

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-14T20:47:29', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '33a2a852-83a2-483b-85aa-4f8391086634'	System	15 Aug 2020 01:47:43
User entered 'None (0)'	System	15 Aug 2020 01:47:43

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:11

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)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-14T20:47:32', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '33a2a852-83a2-483b-85aa-4f8391086634'	System	15 Aug 2020 01:47:43
User entered 'No (N)'	System	15 Aug 2020 01:47:43

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-14T20:47:37', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '33a2a852-83a2-483b-85aa-4f8391086634'	System	15 Aug 2020 01:47:43
User entered '14 Aug 2020 20:47'	System	15 Aug 2020 01:47:43

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered 'Day 4'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-15T21:52:41', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '237f2456-0b91-4832-8aa7-51b09f885620'	System	16 Aug 2020 02:53:13
User entered 'None (0)'	System	16 Aug 2020 02:53:13

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-15T21:52:43', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '237f2456-0b91-4832-8aa7-51b09f885620'	System	16 Aug 2020 02:53:13
User entered 'None (0)'	System	16 Aug 2020 02:53:13

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-15T21:52:45', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '237f2456-0b91-4832-8aa7-51b09f885620'	System	16 Aug 2020 02:53:13
User entered 'None (0)'	System	16 Aug 2020 02:53:13

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-15T21:52:47', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '237f2456-0b91-4832-8aa7-51b09f885620' User entered 'None (0)'	System	16 Aug 2020 02:53:13
	System	16 Aug 2020 02:53:13

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-15T21:52:49', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '237f2456-0b91-4832-8aa7-51b09f885620'	System	16 Aug 2020 02:53:13
User entered 'None (0)'	System	16 Aug 2020 02:53:13

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-15T21:52:51', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '237f2456-0b91-4832-8aa7-51b09f885620'	System	16 Aug 2020 02:53:13
User entered 'None (0)'	System	16 Aug 2020 02:53:13

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:11

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)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-15T21:52:54', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '237f2456-0b91-4832-8aa7-51b09f885620'	System	16 Aug 2020 02:53:13
User entered 'No (N)'	System	16 Aug 2020 02:53:13

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-15T21:53:03', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '237f2456-0b91-4832-8aa7-51b09f885620'	System	16 Aug 2020 02:53:13
User entered '15 Aug 2020 21:53'	System	16 Aug 2020 02:53:13

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered 'Day 5'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-16T19:57:01', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'f0eccb7b-870d-4f11-94b7-09a78279b602'	System	17 Aug 2020 00:57:32
User entered 'None (0)'	System	17 Aug 2020 00:57:32

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-16T19:57:03', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'f0eccb7b-870d-4f11-94b7-09a78279b602'	System	17 Aug 2020 00:57:32
User entered 'None (0)'	System	17 Aug 2020 00:57:32

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-16T19:57:09', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'f0eccb7b-870d-4f11-94b7-09a78279b602'	System	17 Aug 2020 00:57:32
User entered 'None (0)'	System	17 Aug 2020 00:57:32

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-16T19:57:12', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'f0eccb7b-870d-4f11-94b7-09a78279b602'	System	17 Aug 2020 00:57:32
User entered 'None (0)'	System	17 Aug 2020 00:57:32

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-16T19:57:14', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'f0eccb7b-870d-4f11-94b7-09a78279b602'	System	17 Aug 2020 00:57:32
User entered 'None (0)'	System	17 Aug 2020 00:57:32

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-16T19:57:16', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'f0eccb7b-870d-4f11-94b7-09a78279b602'	System	17 Aug 2020 00:57:32
User entered 'None (0)'	System	17 Aug 2020 00:57:32

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:11

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)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-16T19:57:20', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'f0eccb7b-870d-4f11-94b7-09a78279b602'	System	17 Aug 2020 00:57:32
User entered 'No (N)'	System	17 Aug 2020 00:57:32

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-16T19:57:27', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'f0eccb7b-870d-4f11-94b7-09a78279b602'	System	17 Aug 2020 00:57:32
User entered '16 Aug 2020 19:57'	System	17 Aug 2020 00:57:32

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered 'Day 6'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-17T21:06:05', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'a9296e02-be08-4a0a-bad0-33212a360af8'	System	18 Aug 2020 02:06:38
User entered 'None (0)'	System	18 Aug 2020 02:06:38

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-17T21:06:07', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'a9296e02-be08-4a0a-bad0-33212a360af8'	System	18 Aug 2020 02:06:38
User entered 'None (0)'	System	18 Aug 2020 02:06:38

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-17T21:06:09', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'a9296e02-be08-4a0a-bad0-33212a360af8'	System	18 Aug 2020 02:06:38
User entered 'None (0)'	System	18 Aug 2020 02:06:38

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-17T21:06:11', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'a9296e02-be08-4a0a-bad0-33212a360af8'	System	18 Aug 2020 02:06:38
User entered 'None (0)'	System	18 Aug 2020 02:06:38

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-17T21:06:13', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'a9296e02-be08-4a0a-bad0-33212a360af8'	System	18 Aug 2020 02:06:38
User entered 'None (0)'	System	18 Aug 2020 02:06:38

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-17T21:06:15', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'a9296e02-be08-4a0a-bad0-33212a360af8'	System	18 Aug 2020 02:06:38
User entered 'None (0)'	System	18 Aug 2020 02:06:38

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:11

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)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-17T21:06:22', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'a9296e02-be08-4a0a-bad0-33212a360af8'	System	18 Aug 2020 02:06:38
User entered 'No (N)'	System	18 Aug 2020 02:06:38

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-17T21:06:33', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'a9296e02-be08-4a0a-bad0-33212a360af8'	System	18 Aug 2020 02:06:38
User entered '17 Aug 2020 21:06'	System	18 Aug 2020 02:06:38

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered 'Day 7'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-18T19:53:07', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '4ffad915-8581-4ebb-9251-cbca71e581c1'	System	19 Aug 2020 00:53:40
User entered 'None (0)'	System	19 Aug 2020 00:53:40

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-18T19:53:11', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '4ffad915-8581-4ebb-9251-cbca71e581c1'	System	19 Aug 2020 00:53:40
User entered 'None (0)'	System	19 Aug 2020 00:53:40

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-18T19:53:14', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '4ffad915-8581-4ebb-9251-cbca71e581c1'	System	19 Aug 2020 00:53:40
User entered 'None (0)'	System	19 Aug 2020 00:53:40

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-18T19:53:17', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '4ffad915-8581-4ebb-9251-cbca71e581c1'	System	19 Aug 2020 00:53:40
User entered 'None (0)'	System	19 Aug 2020 00:53:40

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-18T19:53:18', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '4ffad915-8581-4ebb-9251-cbca71e581c1'	System	19 Aug 2020 00:53:40
User entered 'None (0)'	System	19 Aug 2020 00:53:40

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-18T19:53:20', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '4ffad915-8581-4ebb-9251-cbca71e581c1'	System	19 Aug 2020 00:53:40
User entered 'None (0)'	System	19 Aug 2020 00:53:40

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:11

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)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-18T19:53:27', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '4ffad915-8581-4ebb-9251-cbca71e581c1'	System	19 Aug 2020 00:53:40
User entered 'No (N)'	System	19 Aug 2020 00:53:40

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-08-18T19:53:34', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '4ffad915-8581-4ebb-9251-cbca71e581c1'	System	19 Aug 2020 00:53:40
User entered '18 Aug 2020 19:53'	System	19 Aug 2020 00:53:40

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 23:47:21

US3032201

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 23:47:21

US3032201

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	20 Aug 2020 17:50:23
	(b) (4)	

US3032201

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '20 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	20 Aug 2020 17:50:23
	(b) (4)	

US3032201

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4)	20 Aug 2020 17:50:23

US3032201

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	20 Aug 2020 17:50:23
	(b) (4)	

US3032201

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	20 Aug 2020 17:50:46

US3032201

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered 'I'	System	20 Aug 2020 17:50:46

US3032201

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	27 Aug 2020 20:13:47
	(b) (4)	

US3032201

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '26 Aug 2020'	Kelsey Kelley (b) (4)	27 Aug 2020 20:13:47

US3032201

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Contact Made (CONTACT MADE)'	Kelsey Kelley (b) (4)	27 Aug 2020 20:13:47

US3032201

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	27 Aug 2020 20:13:47
	(b) (4)	

US3032201

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	27 Aug 2020 20:13:51
	(b) (4)	

US3032201

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered 'I'	System	27 Aug 2020 20:13:51

US3032201

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	03 Sep 2020 23:42:24

US3032201

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	03 Sep 2020 23:42:52
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	03 Sep 2020 23:42:52
User entered '02 Sep 2020' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	03 Sep 2020 23:42:52
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	03 Sep 2020 23:42:24
User entered '26 Aug 2020'	System	03 Sep 2020 23:42:24
	Samantha Wieseler (b) (4)	03 Sep 2020 23:42:24
	(b) (4)	

US3032201

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Contact Made (CONTACT MADE)'	Samantha Wieseler (b) (4)	03 Sep 2020 23:42:24

US3032201

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered empty.	Samantha Wieseler (b) (4)	03 Sep 2020 23:42:24

US3032201

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	03 Sep 2020 23:42:35

US3032201

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered 'I'	System	03 Sep 2020 23:42:35

US3032201

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	10 Sep 2020 20:55:59

US3032201

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '10 Sep 2020'	Linden DeBoer (b) (4)	10 Sep 2020 20:55:59

US3032201

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Clinic (Clinic)'	Linden DeBoer (b) (4)	10 Sep 2020 20:55:59

US3032201

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered 'VISIT2'	System	10 Sep 2020 20:55:59

US3032201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User accepted default value 'Pre-Dose (PREDOSE)'	Samantha Wieseler (b) (4)	10 Sep 2020 21:43:37
	(b) (4)	

US3032201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	10 Sep 2020 21:43:37

US3032201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '10 Sep 2020'	Samantha Wieseler (b) (4)	10 Sep 2020 21:43:37

US3032201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '14:47'	Samantha Wieseler (b) (4)	10 Sep 2020 21:43:37

US3032201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered '10 Sep 2020 14:47'	System	10 Sep 2020 21:43:37

US3032201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '36.9' C	Samantha Wieseler (b) (4)	10 Sep 2020 21:43:37

US3032201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Oral (Oral)'	Samantha Wieseler (b) (4)	10 Sep 2020 21:43:37

US3032201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered empty.	Samantha Wieseler (b) (4)	10 Sep 2020 21:43:37

US3032201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '93'	Samantha Wieseler (b) (4)	10 Sep 2020 21:43:37

US3032201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered 'bpm'	System	10 Sep 2020 21:43:37

US3032201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '14'	Samantha Wieseler (b) (4)	10 Sep 2020 21:43:37

US3032201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered 'breaths/min'	System	10 Sep 2020 21:43:37

US3032201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '119'	Samantha Wieseler (b) (4)	10 Sep 2020 21:43:37

US3032201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered 'mmHg'	System	10 Sep 2020 21:43:37

US3032201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '90'	Samantha Wieseler (b) (4)	10 Sep 2020 21:43:37

US3032201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered 'mmHg'	System	10 Sep 2020 21:43:37

US3032201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User accepted default value 'Post-Dose (POSTDOSE)'	Samantha Wieseler (b) (4)	10 Sep 2020 21:43:37

US3032201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Sep 2020 21:43:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Sep 2020 21:43:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	10 Sep 2020 21:43:42
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Sep 2020 21:43:37
User entered empty.	System	10 Sep 2020 21:43:37
	Samantha Wieseler (b) (4)	10 Sep 2020 21:43:37
	(b) (4)	

US3032201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '10 Sep 2020'	(b) (4) Samantha Wieseler (b) (4)	10 Sep 2020 21:43:37

US3032201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '16:22'	Samantha Wieseler (b) (4)	10 Sep 2020 21:43:37

US3032201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered '10 Sep 2020 16:22'	System	10 Sep 2020 21:43:37

US3032201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '36.5' C	Samantha Wieseler (b) (4)	10 Sep 2020 21:43:37

US3032201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Oral (Oral)'	Samantha Wieseler (b) (4)	10 Sep 2020 21:43:37

US3032201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered empty.	Samantha Wieseler (b) (4)	10 Sep 2020 21:43:37

US3032201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '84'	Samantha Wieseler (b) (4)	10 Sep 2020 21:43:37

US3032201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered 'bpm'	System	10 Sep 2020 21:43:37

US3032201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '14'	Samantha Wieseler (b) (4)	10 Sep 2020 21:43:37

US3032201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered 'breaths/min'	System	10 Sep 2020 21:43:37

US3032201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '130'	Samantha Wieseler (b) (4)	10 Sep 2020 21:43:37

US3032201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered 'mmHg'	System	10 Sep 2020 21:43:37

US3032201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '90'	Samantha Wieseler (b) (4)	10 Sep 2020 21:43:37

US3032201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered 'mmHg'	System	10 Sep 2020 21:43:37

US3032201

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	10 Sep 2020 20:56:07

US3032201

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '10 Sep 2020'	Linden DeBoer (b) (4)	10 Sep 2020 20:56:07

US3032201

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	10 Sep 2020 20:56:18

US3032201

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '10 Sep 2020'	Linden DeBoer (b) (4)	10 Sep 2020 20:56:18

US3032201

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Urine (URINE)'	Linden DeBoer (b) (4)	10 Sep 2020 20:56:18

US3032201

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Negative (NEGATIVE)'	Linden DeBoer (b) (4)	10 Sep 2020 20:56:18

US3032201

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'No (N)'	Linden DeBoer (b) (4)	10 Sep 2020 20:56:18

US3032201

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered empty.	Linden DeBoer (b) (4)	10 Sep 2020 20:56:18

US3032201

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered empty.	Linden DeBoer (b) (4)	10 Sep 2020 20:56:18

US3032201

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered empty.	System	10 Sep 2020 20:56:18

US3032201

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	10 Sep 2020 20:56:42

US3032201

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered empty.	Linden DeBoer (b) (4)	10 Sep 2020 20:56:42

US3032201

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered empty.	Linden DeBoer (b) (4)	10 Sep 2020 20:56:42

US3032201

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 20:56:42

US3032201

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '10 Sep 2020'	Linden DeBoer (b) (4)	10 Sep 2020 20:56:42

US3032201

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '15:50'	Linden DeBoer (b) (4)	10 Sep 2020 20:56:42

US3032201

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered '10 Sep 2020 15:50'	System	10 Sep 2020 20:56:42

US3032201

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Left Arm (LEFT ARM)'	Linden DeBoer (b) (4)	10 Sep 2020 20:56:42

US3032201

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered 'ONCE'	System	10 Sep 2020 20:56:42

US3032201

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 20:56:42

US3032201

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	10 Sep 2020 20:57:21

US3032201

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '10 Sep 2020'	Linden DeBoer (b) (4)	10 Sep 2020 20:57:21

US3032201

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '15:19'	Linden DeBoer (b) (4)	10 Sep 2020 20:57:21

US3032201

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered '10 Sep 2020 15:19'	System	10 Sep 2020 20:57:21

US3032201

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 21:52:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '10 Sep 2020'	Linden DeBoer (b) (4)	10 Sep 2020 20:57:36

US3032201

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:52:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Linden DeBoer (b) (4) (b) (4)	10 Sep 2020 20:57:36

US3032201

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:52:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	10 Sep 2020 20:57:36

US3032201

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:52:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '15:09'	Linden DeBoer (b) (4)	10 Sep 2020 20:57:36

US3032201

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered '10 Sep 2020 15:09'	System	10 Sep 2020 20:57:36

US3032201

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:52:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Linden DeBoer (b) (4) (b) (4)	10 Sep 2020 20:57:36

US3032201

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:52:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'No (N)'	Linden DeBoer (b) (4)	10 Sep 2020 20:57:36

US3032201

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:52:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered empty.	Linden DeBoer (b) (4)	10 Sep 2020 20:57:36

US3032201

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered empty.	System	10 Sep 2020 20:57:36

US3032201

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	10 Sep 2020 20:57:43

US3032201

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered '1'	System	10 Sep 2020 20:57:43

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	10 Sep 2020 20:56:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-10T16:22:32', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '25decdeb-6437-4d17-98aa-94cf5556a1e5'	System	10 Sep 2020 21:22:53
User entered 'Yes (Y)'	System	10 Sep 2020 21:22:53

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-10T16:22:39', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '25decdeb-6437-4d17-98aa-94cf5556a1e5'	System	10 Sep 2020 21:22:53
User entered '97.7'	System	10 Sep 2020 21:22:53

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-10T16:22:42', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '25decdeb-6437-4d17-98aa-94cf5556a1e5'	System	10 Sep 2020 21:22:53
User entered 'No (N)'	System	10 Sep 2020 21:22:53

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-10T16:22:49', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '25decdeb-6437-4d17-98aa-94cf5556a1e5'	System	10 Sep 2020 21:22:53
User entered '10 Sep 2020 16:22'	System	10 Sep 2020 21:22:53

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '10 Sep 2020 16:10'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '10 Sep 2020 18:40'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	10 Sep 2020 20:56:42
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-10T20:04:55', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '1ed94726-63b9-4797-95b2-9b1508bfad92'	System	11 Sep 2020 01:05:37
User entered 'Yes (Y)'	System	11 Sep 2020 01:05:37

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-10T20:05:22', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '1ed94726-63b9-4797-95b2-9b1508bfad92'	System	11 Sep 2020 01:05:37
User entered '97.8'	System	11 Sep 2020 01:05:37

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-10T20:05:25', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '1ed94726-63b9-4797-95b2-9b1508bfad92'	System	11 Sep 2020 01:05:37
User entered 'No (N)'	System	11 Sep 2020 01:05:37

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-10T20:05:30', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '1ed94726-63b9-4797-95b2-9b1508bfad92'	System	11 Sep 2020 01:05:37
User entered '10 Sep 2020 20:05'	System	11 Sep 2020 01:05:37

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '10 Sep 2020 19:35'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	10 Sep 2020 20:56:42
User entered 'Day 2'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:52:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-12T01:14:54', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '06eea45c-39ab-4b3f-b484-07137616ca02'	System	12 Sep 2020 06:23:03
User entered 'Yes (Y)'	System	12 Sep 2020 06:23:03

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:52:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-12T01:22:52', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '06eea45c-39ab-4b3f-b484-07137616ca02'	System	12 Sep 2020 06:23:03
User entered '96.3'	System	12 Sep 2020 06:23:03

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-12T01:22:55', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '06eea45c-39ab-4b3f-b484-07137616ca02'	System	12 Sep 2020 06:23:03
User entered 'No (N)'	System	12 Sep 2020 06:23:03

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:52:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-12T01:23:00', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '06eea45c-39ab-4b3f-b484-07137616ca02'	System	12 Sep 2020 06:23:03
User entered '12 Sep 2020 01:23'	System	12 Sep 2020 06:23:03

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	10 Sep 2020 20:56:42
User entered 'Day 3'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:52:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-12T21:43:10', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '14a686f9-60ca-494d-a75b-2b7f8c177e1c'	System	13 Sep 2020 02:43:52
User entered 'Yes (Y)'	System	13 Sep 2020 02:43:52

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:52:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-12T21:43:15', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '14a686f9-60ca-494d-a75b-2b7f8c177e1c'	System	13 Sep 2020 02:43:52
User entered '96.1'	System	13 Sep 2020 02:43:52

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-12T21:43:17', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '14a686f9-60ca-494d-a75b-2b7f8c177e1c'	System	13 Sep 2020 02:43:52
User entered 'No (N)'	System	13 Sep 2020 02:43:52

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:52:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-12T21:43:22', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '14a686f9-60ca-494d-a75b-2b7f8c177e1c'	System	13 Sep 2020 02:43:52
User entered '12 Sep 2020 21:43'	System	13 Sep 2020 02:43:52

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	10 Sep 2020 20:56:42
User entered 'Day 4'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:52:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-13T22:59:56', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '99b1a5fb-48c5-4e56-9c3e-73d45c24f831'	System	14 Sep 2020 04:00:19
User entered 'Yes (Y)'	System	14 Sep 2020 04:00:19

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:52:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-13T23:00:04', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '99b1a5fb-48c5-4e56-9c3e-73d45c24f831'	System	14 Sep 2020 04:00:19
User entered '97.5'	System	14 Sep 2020 04:00:19

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-13T23:00:08', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '99b1a5fb-48c5-4e56-9c3e-73d45c24f831'	System	14 Sep 2020 04:00:19
User entered 'No (N)'	System	14 Sep 2020 04:00:19

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:52:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-13T23:00:14', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '99b1a5fb-48c5-4e56-9c3e-73d45c24f831'	System	14 Sep 2020 04:00:19
User entered '13 Sep 2020 23:00'	System	14 Sep 2020 04:00:19

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	10 Sep 2020 20:56:42
User entered 'Day 5'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:52:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-14T23:53:14', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '43ccf41d-a786-4f7d-80aa-185153ea067f'	System	15 Sep 2020 04:53:39
User entered 'Yes (Y)'	System	15 Sep 2020 04:53:39

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:52:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-14T23:53:21', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '43ccf41d-a786-4f7d-80aa-185153ea067f'	System	15 Sep 2020 04:53:39
User entered '96.6'	System	15 Sep 2020 04:53:39

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-14T23:53:24', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '43ccf41d-a786-4f7d-80aa-185153ea067f'	System	15 Sep 2020 04:53:39
User entered 'No (N)'	System	15 Sep 2020 04:53:39

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:52:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-14T23:53:31', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '43ccf41d-a786-4f7d-80aa-185153ea067f'	System	15 Sep 2020 04:53:39
User entered '14 Sep 2020 23:53'	System	15 Sep 2020 04:53:39

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	10 Sep 2020 20:56:42
User entered 'Day 6'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:52:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-15T20:28:47', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'e0f11b22-d1ae-4c7c-9939-68afc30926fe'	System	16 Sep 2020 01:29:16
User entered 'Yes (Y)'	System	16 Sep 2020 01:29:16

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:52:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-15T20:28:54', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'e0f11b22-d1ae-4c7c-9939-68afc30926fe' User entered '98.1'	System	16 Sep 2020 01:29:16
	System	16 Sep 2020 01:29:16

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-15T20:28:57', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'e0f11b22-d1ae-4c7c-9939-68afc30926fe'	System	16 Sep 2020 01:29:16
User entered 'No (N)'	System	16 Sep 2020 01:29:16

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:52:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-15T20:29:08', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'e0f11b22-d1ae-4c7c-9939-68afc30926fe'	System	16 Sep 2020 01:29:16
User entered '15 Sep 2020 20:29'	System	16 Sep 2020 01:29:16

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	10 Sep 2020 20:56:42
User entered 'Day 7'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:52:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-16T22:00:58', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '6dda8604-7baa-437b-bb8b-5514f276d9c7'	System	17 Sep 2020 03:01:16
User entered 'Yes (Y)'	System	17 Sep 2020 03:01:16

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:52:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-16T22:01:04', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '6dda8604-7baa-437b-bb8b-5514f276d9c7'	System	17 Sep 2020 03:01:16
User entered '96.6'	System	17 Sep 2020 03:01:16

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-16T22:01:07', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '6dda8604-7baa-437b-bb8b-5514f276d9c7'	System	17 Sep 2020 03:01:16
User entered 'No (N)'	System	17 Sep 2020 03:01:16

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:52:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-16T22:01:11', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '6dda8604-7baa-437b-bb8b-5514f276d9c7'	System	17 Sep 2020 03:01:16
User entered '16 Sep 2020 22:01'	System	17 Sep 2020 03:01:16

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	10 Sep 2020 20:56:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-10T16:22:55', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '01a255fc-dd90-4b4c-90e2-8130dce39b31'	System	10 Sep 2020 21:23:21
User entered 'None (1)'	System	10 Sep 2020 21:23:21

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-10T16:22:57', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '01a255fc-dd90-4b4c-90e2-8130dce39b31'	System	10 Sep 2020 21:23:21
User entered 'No (N)'	System	10 Sep 2020 21:23:21

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-10T16:23:02', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '01a255fc-dd90-4b4c-90e2-8130dce39b31'	System	10 Sep 2020 21:23:21
User entered 'No (N)'	System	10 Sep 2020 21:23:21

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-10T16:23:04', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '01a255fc-dd90-4b4c-90e2-8130dce39b31'	System	10 Sep 2020 21:23:21
User entered 'None (1)'	System	10 Sep 2020 21:23:21

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-10T16:23:15', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '01a255fc-dd90-4b4c-90e2-8130dce39b31'	System	10 Sep 2020 21:23:21
User entered '10 Sep 2020 16:23'	System	10 Sep 2020 21:23:21

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '10 Sep 2020 16:10'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '10 Sep 2020 18:40'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	10 Sep 2020 20:56:42
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-10T20:05:39', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '6bab5256-ee56-4661-b4aa-86b7c1e2f691'	System	11 Sep 2020 01:06:12
User entered 'None (1)'	System	11 Sep 2020 01:06:12

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-10T20:05:42', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '6bab5256-ee56-4661-b4aa-86b7c1e2f691'	System	11 Sep 2020 01:06:12
User entered 'No (N)'	System	11 Sep 2020 01:06:12

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-10T20:05:44', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '6bab5256-ee56-4661-b4aa-86b7c1e2f691'	System	11 Sep 2020 01:06:12
User entered 'No (N)'	System	11 Sep 2020 01:06:12

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-10T20:05:47', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '6bab5256-ee56-4661-b4aa-86b7c1e2f691'	System	11 Sep 2020 01:06:12
User entered 'None (1)'	System	11 Sep 2020 01:06:12

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-10T20:05:54', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '6bab5256-ee56-4661-b4aa-86b7c1e2f691'	System	11 Sep 2020 01:06:12
User entered '10 Sep 2020 20:05'	System	11 Sep 2020 01:06:12

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '10 Sep 2020 19:35'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	10 Sep 2020 20:56:42
User entered 'Day 2'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:52:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-12T01:23:16', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'f5e5f9c5-d091-4c04-afdd-c02c9078d9df'	System	12 Sep 2020 06:23:37
User entered 'None (1)'	System	12 Sep 2020 06:23:37

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:52:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-12T01:23:19', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'f5e5f9c5-d091-4c04-afdd-c02c9078d9df'	System	12 Sep 2020 06:23:37
User entered 'No (N)'	System	12 Sep 2020 06:23:37

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-12T01:23:23', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'f5e5f9c5-d091-4c04-afdd-c02c9078d9df'	System	12 Sep 2020 06:23:37
User entered 'No (N)'	System	12 Sep 2020 06:23:37

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:52:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-12T01:23:26', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'f5e5f9c5-d091-4c04-afdd-c02c9078d9df'	System	12 Sep 2020 06:23:37
User entered 'None (1)'	System	12 Sep 2020 06:23:37

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:52:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-12T01:23:33', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'f5e5f9c5-d091-4c04-afdd-c02c9078d9df'	System	12 Sep 2020 06:23:37
User entered '12 Sep 2020 01:23'	System	12 Sep 2020 06:23:37

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	10 Sep 2020 20:56:42
User entered 'Day 3'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:52:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-12T21:43:34', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '898242f4-7517-4387-8cff-542ada388011'	System	13 Sep 2020 02:43:58
User entered 'None (1)'	System	13 Sep 2020 02:43:58

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:52:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-12T21:43:36', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '898242f4-7517-4387-8cff-542ada388011'	System	13 Sep 2020 02:43:58
User entered 'No (N)'	System	13 Sep 2020 02:43:58

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-12T21:43:40', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '898242f4-7517-4387-8cff-542ada388011'	System	13 Sep 2020 02:43:58
User entered 'No (N)'	System	13 Sep 2020 02:43:58

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:52:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-12T21:43:43', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '898242f4-7517-4387-8cff-542ada388011'	System	13 Sep 2020 02:43:58
User entered 'None (1)'	System	13 Sep 2020 02:43:58

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:52:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-12T21:43:49', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '898242f4-7517-4387-8cff-542ada388011'	System	13 Sep 2020 02:43:58
User entered '12 Sep 2020 21:43'	System	13 Sep 2020 02:43:58

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	10 Sep 2020 20:56:42
User entered 'Day 4'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:52:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-13T23:00:21', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '5dee5a05-d129-4bcf-89c6-077b0d38a897'	System	14 Sep 2020 04:00:42
User entered 'None (1)'	System	14 Sep 2020 04:00:42

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-13T23:00:24', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '5dee5a05-d129-4bcf-89c6-077b0d38a897'	System	14 Sep 2020 04:00:42
User entered 'No (N)'	System	14 Sep 2020 04:00:42

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-13T23:00:27', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '5dee5a05-d129-4bcf-89c6-077b0d38a897'	System	14 Sep 2020 04:00:42
User entered 'No (N)'	System	14 Sep 2020 04:00:42

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:52:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-13T23:00:30', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '5dee5a05-d129-4bcf-89c6-077b0d38a897'	System	14 Sep 2020 04:00:42
User entered 'None (1)'	System	14 Sep 2020 04:00:42

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:52:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-13T23:00:36', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '5dee5a05-d129-4bcf-89c6-077b0d38a897'	System	14 Sep 2020 04:00:42
User entered '13 Sep 2020 23:00'	System	14 Sep 2020 04:00:42

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	10 Sep 2020 20:56:42
User entered 'Day 5'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:52:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-14T23:53:38', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '5bd60887-3cf0-476f-bf03-89cf1d9c8a3c'	System	15 Sep 2020 04:54:06
User entered 'None (1)'	System	15 Sep 2020 04:54:06

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:52:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-14T23:53:41', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '5bd60887-3cf0-476f-bf03-89cf1d9c8a3c'	System	15 Sep 2020 04:54:06
User entered 'No (N)'	System	15 Sep 2020 04:54:06

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-14T23:53:43', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '5bd60887-3cf0-476f-bf03-89cf1d9c8a3c'	System	15 Sep 2020 04:54:06
User entered 'No (N)'	System	15 Sep 2020 04:54:06

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:52:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-14T23:53:46', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '5bd60887-3cf0-476f-bf03-89cf1d9c8a3c'	System	15 Sep 2020 04:54:06
User entered 'None (1)'	System	15 Sep 2020 04:54:06

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:52:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-14T23:53:58', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '5bd60887-3cf0-476f-bf03-89cf1d9c8a3c'	System	15 Sep 2020 04:54:06
User entered '14 Sep 2020 23:53'	System	15 Sep 2020 04:54:06

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	10 Sep 2020 20:56:42
User entered 'Day 6'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:52:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-15T20:29:13', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '1719aab0-c221-4c16-8404-8f553c060f1d'	System	16 Sep 2020 01:29:37
User entered 'None (1)'	System	16 Sep 2020 01:29:37

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-15T20:29:16', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '1719aab0-c221-4c16-8404-8f553c060f1d'	System	16 Sep 2020 01:29:37
User entered 'No (N)'	System	16 Sep 2020 01:29:37

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-15T20:29:18', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '1719aab0-c221-4c16-8404-8f553c060f1d'	System	16 Sep 2020 01:29:37
User entered 'No (N)'	System	16 Sep 2020 01:29:37

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:52:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-15T20:29:21', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '1719aab0-c221-4c16-8404-8f553c060f1d'	System	16 Sep 2020 01:29:37
User entered 'None (1)'	System	16 Sep 2020 01:29:37

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:52:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-15T20:29:29', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '1719aab0-c221-4c16-8404-8f553c060f1d'	System	16 Sep 2020 01:29:37
User entered '15 Sep 2020 20:29'	System	16 Sep 2020 01:29:37

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	10 Sep 2020 20:56:42
User entered 'Day 7'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:52:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-16T22:01:16', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '0190eb41-69ac-4791-9f0d-40f1bf53e2d2'	System	17 Sep 2020 03:01:39
User entered 'None (1)'	System	17 Sep 2020 03:01:39

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:52:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-16T22:01:19', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '0190eb41-69ac-4791-9f0d-40f1bf53e2d2'	System	17 Sep 2020 03:01:39
User entered 'No (N)'	System	17 Sep 2020 03:01:39

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-16T22:01:21', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '0190eb41-69ac-4791-9f0d-40f1bf53e2d2'	System	17 Sep 2020 03:01:39
User entered 'No (N)'	System	17 Sep 2020 03:01:39

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:52:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-16T22:01:26', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '0190eb41-69ac-4791-9f0d-40f1bf53e2d2'	System	17 Sep 2020 03:01:39
User entered 'None (1)'	System	17 Sep 2020 03:01:39

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:52:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-16T22:01:34', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '0190eb41-69ac-4791-9f0d-40f1bf53e2d2'	System	17 Sep 2020 03:01:39
User entered '16 Sep 2020 22:01'	System	17 Sep 2020 03:01:39

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	10 Sep 2020 20:56:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-10T16:23:20', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '9e670c06-977d-48cc-b029-2688e0379afa'	System	10 Sep 2020 21:23:53
User entered 'None (0)'	System	10 Sep 2020 21:23:53

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-10T16:23:21', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '9e670c06-977d-48cc-b029-2688e0379afa'	System	10 Sep 2020 21:23:53
User entered 'None (0)'	System	10 Sep 2020 21:23:53

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-10T16:23:23', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '9e670c06-977d-48cc-b029-2688e0379afa'	System	10 Sep 2020 21:23:53
User entered 'None (0)'	System	10 Sep 2020 21:23:53

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-10T16:23:25', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '9e670c06-977d-48cc-b029-2688e0379afa' User entered 'None (0)'	System	10 Sep 2020 21:23:53
	System	10 Sep 2020 21:23:53

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-10T16:23:27', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '9e670c06-977d-48cc-b029-2688e0379afa' User entered 'None (0)'	System	10 Sep 2020 21:23:53
	System	10 Sep 2020 21:23:53

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-10T16:23:29', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '9e670c06-977d-48cc-b029-2688e0379afa'	System	10 Sep 2020 21:23:53
User entered 'None (0)'	System	10 Sep 2020 21:23:53

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

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)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-10T16:23:35', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '9e670c06-977d-48cc-b029-2688e0379afa'	System	10 Sep 2020 21:23:53
User entered 'No (N)'	System	10 Sep 2020 21:23:53

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-10T16:23:48', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '9e670c06-977d-48cc-b029-2688e0379afa'	System	10 Sep 2020 21:23:53
User entered '10 Sep 2020 16:23'	System	10 Sep 2020 21:23:53

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '10 Sep 2020 16:10'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '10 Sep 2020 18:40'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	10 Sep 2020 20:56:42
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-10T20:05:58', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'be9390bd-6ac0-4528-bae9-16cdb5ea77c1'	System	11 Sep 2020 01:06:24
User entered 'None (0)'	System	11 Sep 2020 01:06:24

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-10T20:06:03', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'be9390bd-6ac0-4528-bae9-16cdb5ea77c1'	System	11 Sep 2020 01:06:24
User entered 'None (0)'	System	11 Sep 2020 01:06:24

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-10T20:06:04', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'be9390bd-6ac0-4528-bae9-16cdb5ea77c1'	System	11 Sep 2020 01:06:24
User entered 'None (0)'	System	11 Sep 2020 01:06:24

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-10T20:06:06', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'be9390bd-6ac0-4528-bae9-16cdb5ea77c1'	System	11 Sep 2020 01:06:24
User entered 'None (0)'	System	11 Sep 2020 01:06:24

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-10T20:06:08', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'be9390bd-6ac0-4528-bae9-16cdb5ea77c1'	System	11 Sep 2020 01:06:24
User entered 'None (0)'	System	11 Sep 2020 01:06:24

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-10T20:06:09', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'be9390bd-6ac0-4528-bae9-16cdb5ea77c1'	System	11 Sep 2020 01:06:24
User entered 'None (0)'	System	11 Sep 2020 01:06:24

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

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)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-10T20:06:12', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'be9390bd-6ac0-4528-bae9-16cdb5ea77c1'	System	11 Sep 2020 01:06:24
User entered 'No (N)'	System	11 Sep 2020 01:06:24

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-10T20:06:19', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'be9390bd-6ac0-4528-bae9-16cdb5ea77c1'	System	11 Sep 2020 01:06:24
User entered '10 Sep 2020 20:06'	System	11 Sep 2020 01:06:24

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '10 Sep 2020 19:35'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	10 Sep 2020 20:56:42
User entered 'Day 2'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-12T01:23:38', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'f7af19fd-2a09-43c8-af33-fa1092fda6e6'	System	12 Sep 2020 06:24:18
User entered 'None (0)'	System	12 Sep 2020 06:24:18

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-12T01:23:41', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'f7af19fd-2a09-43c8-af33-fa1092fda6e6'	System	12 Sep 2020 06:24:18
User entered 'None (0)'	System	12 Sep 2020 06:24:18

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-12T01:23:43', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'f7af19fd-2a09-43c8-af33-fa1092fda6e6'	System	12 Sep 2020 06:24:18
User entered 'None (0)'	System	12 Sep 2020 06:24:18

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-12T01:23:45', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'f7af19fd-2a09-43c8-af33-fa1092fda6e6'	System	12 Sep 2020 06:24:18
User entered 'None (0)'	System	12 Sep 2020 06:24:18

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-12T01:23:47', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'f7af19fd-2a09-43c8-af33-fa1092fda6e6'	System	12 Sep 2020 06:24:18
User entered 'None (0)'	System	12 Sep 2020 06:24:18

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-12T01:23:49', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'f7af19fd-2a09-43c8-af33-fa1092fda6e6'	System	12 Sep 2020 06:24:18
User entered 'None (0)'	System	12 Sep 2020 06:24:18

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:11

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)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-12T01:23:53', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'f7af19fd-2a09-43c8-af33-fa1092fda6e6'	System	12 Sep 2020 06:24:18
User entered 'No (N)'	System	12 Sep 2020 06:24:18

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-12T01:24:12', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'f7af19fd-2a09-43c8-af33-fa1092fda6e6'	System	12 Sep 2020 06:24:18
User entered '12 Sep 2020 01:24'	System	12 Sep 2020 06:24:18

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	10 Sep 2020 20:56:42
User entered 'Day 3'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-12T21:43:54', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'a354e171-f4fb-418f-a8d2-0ea511c6792a'	System	13 Sep 2020 02:44:55
User entered 'None (0)'	System	13 Sep 2020 02:44:55

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-12T21:44:00', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'a354e171-f4fb-418f-a8d2-0ea511c6792a'	System	13 Sep 2020 02:44:55
User entered 'None (0)'	System	13 Sep 2020 02:44:55

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-12T21:44:02', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'a354e171-f4fb-418f-a8d2-0ea511c6792a' User entered 'None (0)'	System	13 Sep 2020 02:44:55
	System	13 Sep 2020 02:44:55

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-12T21:44:08', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'a354e171-f4fb-418f-a8d2-0ea511c6792a'	System	13 Sep 2020 02:44:55
User entered 'None (0)'	System	13 Sep 2020 02:44:55

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-12T21:44:11', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'a354e171-f4fb-418f-a8d2-0ea511c6792a'	System	13 Sep 2020 02:44:55
User entered 'None (0)'	System	13 Sep 2020 02:44:55

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-12T21:44:12', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'a354e171-f4fb-418f-a8d2-0ea511c6792a'	System	13 Sep 2020 02:44:55
User entered 'None (0)'	System	13 Sep 2020 02:44:55

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:11

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)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-12T21:44:16', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'a354e171-f4fb-418f-a8d2-0ea511c6792a'	System	13 Sep 2020 02:44:55
User entered 'No (N)'	System	13 Sep 2020 02:44:55

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-12T21:44:49', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'a354e171-f4fb-418f-a8d2-0ea511c6792a'	System	13 Sep 2020 02:44:55
User entered '12 Sep 2020 21:44'	System	13 Sep 2020 02:44:55

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	10 Sep 2020 20:56:42
User entered 'Day 4'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-13T23:00:44', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'ed73ba91-b507-424a-b96f-a7735b83ab35'	System	14 Sep 2020 04:01:11
User entered 'None (0)'	System	14 Sep 2020 04:01:11

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-13T23:00:47', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'ed73ba91-b507-424a-b96f-a7735b83ab35'	System	14 Sep 2020 04:01:11
User entered 'None (0)'	System	14 Sep 2020 04:01:11

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-13T23:00:49', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'ed73ba91-b507-424a-b96f-a7735b83ab35'	System	14 Sep 2020 04:01:11
User entered 'None (0)'	System	14 Sep 2020 04:01:11

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-13T23:00:50', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'ed73ba91-b507-424a-b96f-a7735b83ab35'	System	14 Sep 2020 04:01:11
User entered 'None (0)'	System	14 Sep 2020 04:01:11

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-13T23:00:52', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'ed73ba91-b507-424a-b96f-a7735b83ab35'	System	14 Sep 2020 04:01:11
User entered 'None (0)'	System	14 Sep 2020 04:01:11

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-13T23:00:54', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'ed73ba91-b507-424a-b96f-a7735b83ab35'	System	14 Sep 2020 04:01:11
User entered 'None (0)'	System	14 Sep 2020 04:01:11

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:11

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)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-13T23:00:57', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'ed73ba91-b507-424a-b96f-a7735b83ab35'	System	14 Sep 2020 04:01:11
User entered 'No (N)'	System	14 Sep 2020 04:01:11

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-13T23:01:04', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'ed73ba91-b507-424a-b96f-a7735b83ab35'	System	14 Sep 2020 04:01:11
User entered '13 Sep 2020 23:01'	System	14 Sep 2020 04:01:11

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	10 Sep 2020 20:56:42
User entered 'Day 5'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-14T23:54:04', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '7c64d221-afe9-4623-bebb-5dfcd5da7cd4'	System	15 Sep 2020 04:54:39
User entered 'None (0)'	System	15 Sep 2020 04:54:39

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-14T23:54:06', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '7c64d221-afe9-4623-bebb-5dfcd5da7cd4'	System	15 Sep 2020 04:54:39
User entered 'None (0)'	System	15 Sep 2020 04:54:39

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-14T23:54:09', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '7c64d221-afe9-4623-bebb-5dfcd5da7cd4'	System	15 Sep 2020 04:54:39
User entered 'None (0)'	System	15 Sep 2020 04:54:39

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-14T23:54:11', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '7c64d221-afe9-4623-bebb-5dfcd5da7cd4'	System	15 Sep 2020 04:54:39
User entered 'None (0)'	System	15 Sep 2020 04:54:39

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-14T23:54:13', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '7c64d221-afe9-4623-bebb-5dfcd5da7cd4'	System	15 Sep 2020 04:54:39
User entered 'None (0)'	System	15 Sep 2020 04:54:39

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-14T23:54:14', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '7c64d221-afe9-4623-bebb-5dfcd5da7cd4'	System	15 Sep 2020 04:54:39
User entered 'None (0)'	System	15 Sep 2020 04:54:39

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:11

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)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-14T23:54:17', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '7c64d221-afe9-4623-bebb-5dfcd5da7cd4'	System	15 Sep 2020 04:54:39
User entered 'No (N)'	System	15 Sep 2020 04:54:39

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-14T23:54:33', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '7c64d221-afe9-4623-bebb-5dfcd5da7cd4'	System	15 Sep 2020 04:54:39
User entered '14 Sep 2020 23:54'	System	15 Sep 2020 04:54:39

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	10 Sep 2020 20:56:42
User entered 'Day 6'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-15T20:29:33', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'ae5f41ef-27ba-46c6-83b2-43a3a5095bc7'	System	16 Sep 2020 01:30:08
User entered 'None (0)'	System	16 Sep 2020 01:30:08

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-15T20:29:35', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'ae5f41ef-27ba-46c6-83b2-43a3a5095bc7'	System	16 Sep 2020 01:30:08
User entered 'None (0)'	System	16 Sep 2020 01:30:08

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-15T20:29:37', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'ae5f41ef-27ba-46c6-83b2-43a3a5095bc7'	System	16 Sep 2020 01:30:08
User entered 'None (0)'	System	16 Sep 2020 01:30:08

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-15T20:29:38', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'ae5f41ef-27ba-46c6-83b2-43a3a5095bc7'	System	16 Sep 2020 01:30:08
User entered 'None (0)'	System	16 Sep 2020 01:30:08

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-15T20:29:41', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'ae5f41ef-27ba-46c6-83b2-43a3a5095bc7'	System	16 Sep 2020 01:30:08
User entered 'None (0)'	System	16 Sep 2020 01:30:08

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-15T20:29:43', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'ae5f41ef-27ba-46c6-83b2-43a3a5095bc7'	System	16 Sep 2020 01:30:08
User entered 'None (0)'	System	16 Sep 2020 01:30:08

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:11

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)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-15T20:29:50', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'ae5f41ef-27ba-46c6-83b2-43a3a5095bc7'	System	16 Sep 2020 01:30:08
User entered 'No (N)'	System	16 Sep 2020 01:30:08

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-15T20:30:01', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'ae5f41ef-27ba-46c6-83b2-43a3a5095bc7'	System	16 Sep 2020 01:30:08
User entered '15 Sep 2020 20:30'	System	16 Sep 2020 01:30:08

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	10 Sep 2020 20:56:42
User entered 'Day 7'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-16T22:01:39', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '9f3593b0-0968-48f6-9d63-6d7cee351afc'	System	17 Sep 2020 03:02:07
User entered 'None (0)'	System	17 Sep 2020 03:02:07

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-16T22:01:40', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '9f3593b0-0968-48f6-9d63-6d7cee351afc'	System	17 Sep 2020 03:02:07
User entered 'None (0)'	System	17 Sep 2020 03:02:07

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-16T22:01:41', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '9f3593b0-0968-48f6-9d63-6d7cee351afc'	System	17 Sep 2020 03:02:07
User entered 'None (0)'	System	17 Sep 2020 03:02:07

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-16T22:01:43', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '9f3593b0-0968-48f6-9d63-6d7cee351afc'	System	17 Sep 2020 03:02:07
User entered 'None (0)'	System	17 Sep 2020 03:02:07

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-16T22:01:44', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '9f3593b0-0968-48f6-9d63-6d7cee351afc'	System	17 Sep 2020 03:02:07
User entered 'None (0)'	System	17 Sep 2020 03:02:07

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-16T22:01:46', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '9f3593b0-0968-48f6-9d63-6d7cee351afc'	System	17 Sep 2020 03:02:07
User entered 'None (0)'	System	17 Sep 2020 03:02:07

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:11

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)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-16T22:01:49', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '9f3593b0-0968-48f6-9d63-6d7cee351afc'	System	17 Sep 2020 03:02:07
User entered 'No (N)'	System	17 Sep 2020 03:02:07

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-09-16T22:02:01', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '9f3593b0-0968-48f6-9d63-6d7cee351afc'	System	17 Sep 2020 03:02:07
User entered '16 Sep 2020 22:02'	System	17 Sep 2020 03:02:07

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 20:56:42

US3032201

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 20:56:42

US3032201

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	17 Sep 2020 16:45:20

US3032201

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '17 Sep 2020'	Samantha Wieseler (b) (4)	17 Sep 2020 16:45:20

US3032201

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Contact Made (CONTACT MADE)'	Samantha Wieseler (b) (4)	17 Sep 2020 16:45:20

US3032201

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered empty.	Samantha Wieseler (b) (4)	17 Sep 2020 16:45:20

US3032201

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	17 Sep 2020 16:45:25

US3032201

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered 'I'	System	17 Sep 2020 16:45:25

US3032201

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	25 Sep 2020 21:27:48

US3032201

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered '25 Sep 2020'	Kelsey Kelley (b) (4)	25 Sep 2020 21:27:48

US3032201

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Contact Made (CONTACT MADE)'	Kelsey Kelley (b) (4)	25 Sep 2020 21:27:48

US3032201

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered empty.	Kelsey Kelley (b) (4)	25 Sep 2020 21:27:48

US3032201

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	25 Sep 2020 21:27:51

US3032201

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered 'I'	System	25 Sep 2020 21:27:51

US3032201

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:17:11
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	02 Oct 2020 20:06:47

US3032201

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:17:11
User entered '1 Oct 2020'	(b) (4) Kelsey Kelley (b) (4)	02 Oct 2020 20:06:47
	(b) (4)	

US3032201

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:17:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4)	02 Oct 2020 20:06:47

US3032201

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:17:11
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Oct 2020 20:06:47

US3032201

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:17:11
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	02 Oct 2020 20:06:50

US3032201

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered 'I'	System	02 Oct 2020 20:06:50

US3032201

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:51:16
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	15 Oct 2020 14:16:02

US3032201

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:51:16
User entered '15 Oct 2020'	(b) (4) Kelsey Kelley (b) (4)	15 Oct 2020 14:16:02
	(b) (4)	

US3032201

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:51:16
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Oct 2020 14:16:02

US3032201

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered 'VISIT3'	System	15 Oct 2020 14:16:02

US3032201

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:51:16
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	15 Oct 2020 14:16:32

US3032201

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:51:16
User entered '15 Oct 2020'	Kelsey Kelley (b) (4)	15 Oct 2020 14:16:32

US3032201

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:51:16
User entered '07:58'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Oct 2020 14:16:32

US3032201

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered '15 Oct 2020 07:58'	System	15 Oct 2020 14:16:32

US3032201

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:51:16
User entered '36.6' C	(b) (4) Kelsey Kelley (b) (4)	15 Oct 2020 14:16:32

US3032201

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:51:16
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	15 Oct 2020 14:16:32

US3032201

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:51:16
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	15 Oct 2020 14:16:32

US3032201

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:51:16
User entered '81'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Oct 2020 14:16:32

US3032201

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered 'bpm'	System	15 Oct 2020 14:16:32

US3032201

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:51:16
User entered '16'	(b) (4) Kelsey Kelley (b) (4)	15 Oct 2020 14:16:32

US3032201

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered 'breaths/min'	System	15 Oct 2020 14:16:32

US3032201

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:51:16
User entered '138'	(b) (4) Kelsey Kelley (b) (4)	15 Oct 2020 14:16:32

US3032201

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered 'mmHg'	System	15 Oct 2020 14:16:32

US3032201

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:51:16
User entered '85'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Oct 2020 14:16:32

US3032201

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered 'mmHg'	System	15 Oct 2020 14:16:32

US3032201

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40

US3032201

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40

US3032201

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:51:16
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	15 Oct 2020 14:16:40

US3032201

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:51:16
User entered '15 Oct 2020'	Kelsey Kelley (b) (4)	15 Oct 2020 14:16:40

US3032201

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:51:16
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	15 Oct 2020 14:17:00

US3032201

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:51:16
User entered '15 Oct 2020'	(b) (4) Kelsey Kelley (b) (4)	15 Oct 2020 14:17:00
	(b) (4)	

US3032201

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:51:16
User entered '08:14'	(b) (4) Kelsey Kelley (b) (4)	15 Oct 2020 14:17:00

US3032201

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered '15 Oct 2020 08:14'	System	15 Oct 2020 14:17:00

US3032201

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:51:16
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	15 Oct 2020 14:17:02

US3032201

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered '1'	System	15 Oct 2020 14:17:02

US3032201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered 'Day 64'	System	12 Aug 2020 23:47:21

US3032201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-10-13T17:08:17', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '04dc95bf-0e8c-4661-bb9b-6886a7be51c8'	System	13 Oct 2020 22:08:41
User entered 'No (N)'	System	13 Oct 2020 22:08:41

US3032201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Have you been exposed to someone with known SARS-CoV-2 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)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-10-13T17:08:22', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '04dc95bf-0e8c-4661-bb9b-6886a7be51c8'	System	13 Oct 2020 22:08:41
User entered 'No (N)'	System	13 Oct 2020 22:08:41

US3032201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-10-13T17:08:33', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '04dc95bf-0e8c-4661-bb9b-6886a7be51c8'	System	13 Oct 2020 22:08:41
User entered '13 Oct 2020 17:08:33'	System	13 Oct 2020 22:08:41

US3032201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered '12 Oct 2020 00:01'	System	12 Aug 2020 23:47:21

US3032201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered '16 Oct 2020 23:59'	System	12 Aug 2020 23:47:21

US3032201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered 'Day 71'	System	12 Aug 2020 23:47:21

US3032201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-10-19T06:51:02', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'cd7f3460-289c-4b3c-b5f2-bfca19e7eb06'	System	19 Oct 2020 11:51:36
User entered 'No (N)'	System	19 Oct 2020 11:51:36

US3032201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Have you been exposed to someone with known SARS-CoV-2 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)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-10-19T06:51:10', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'cd7f3460-289c-4b3c-b5f2-bfca19e7eb06'	System	19 Oct 2020 11:51:36
User entered 'No (N)'	System	19 Oct 2020 11:51:36

US3032201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-10-19T06:51:26', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'cd7f3460-289c-4b3c-b5f2-bfca19e7eb06'	System	19 Oct 2020 11:51:36
User entered '19 Oct 2020 06:51:26'	System	19 Oct 2020 11:51:36

US3032201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered '19 Oct 2020 00:01'	System	12 Aug 2020 23:47:21

US3032201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered '23 Oct 2020 23:59'	System	12 Aug 2020 23:47:21

US3032201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered 'Day 78'	System	12 Aug 2020 23:47:21

US3032201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-10-26T05:44:16', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'd95213b2-6350-4deb-a679-59417afcd502'	System	26 Oct 2020 10:44:42
User entered 'No (N)'	System	26 Oct 2020 10:44:42

US3032201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you been exposed to someone with known SARS-CoV-2 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)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-10-26T05:44:23', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'd95213b2-6350-4deb-a679-59417afcd502'	System	26 Oct 2020 10:44:42
User entered 'No (N)'	System	26 Oct 2020 10:44:42

US3032201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-10-26T05:44:36', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'd95213b2-6350-4deb-a679-59417afcd502'	System	26 Oct 2020 10:44:42
User entered '26 Oct 2020 05:44:36'	System	26 Oct 2020 10:44:42

US3032201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered '26 Oct 2020 00:01'	System	12 Aug 2020 23:47:21

US3032201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered '30 Oct 2020 23:59'	System	12 Aug 2020 23:47:21

US3032201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered 'Day 92'	System	12 Aug 2020 23:47:21

US3032201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-11-09T06:30:43', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '96be9f4d-8cf6-432e-b698-cbcf230dfa8a'	System	09 Nov 2020 12:31:29
User entered 'No (N)'	System	09 Nov 2020 12:31:29

US3032201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you been exposed to someone with known SARS-CoV-2 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)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-11-09T06:30:58', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '96be9f4d-8cf6-432e-b698-cbcf230dfa8a'	System	09 Nov 2020 12:31:29
User entered 'No (N)'	System	09 Nov 2020 12:31:29

US3032201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-11-09T06:31:19', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '96be9f4d-8cf6-432e-b698-cbcf230dfa8a'	System	09 Nov 2020 12:31:29
User entered '09 Nov 2020 06:31:19'	System	09 Nov 2020 12:31:29

US3032201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered '09 Nov 2020 00:01'	System	12 Aug 2020 23:47:21

US3032201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered '13 Nov 2020 23:59'	System	12 Aug 2020 23:47:21

US3032201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered 'Day 99'	System	12 Aug 2020 23:47:21

US3032201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-11-18T08:28:56', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '7075431a-7ccd-4f19-8481-b82481ea176c'	System	18 Nov 2020 14:29:14
User entered 'No (N)'	System	18 Nov 2020 14:29:14

US3032201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you been exposed to someone with known SARS-CoV-2 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)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-11-18T08:29:01', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '7075431a-7ccd-4f19-8481-b82481ea176c'	System	18 Nov 2020 14:29:14
User entered 'No (N)'	System	18 Nov 2020 14:29:14

US3032201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-11-18T08:29:08', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '7075431a-7ccd-4f19-8481-b82481ea176c'	System	18 Nov 2020 14:29:14
User entered '18 Nov 2020 08:29:08'	System	18 Nov 2020 14:29:14

US3032201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered '16 Nov 2020 00:01'	System	12 Aug 2020 23:47:21

US3032201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:13
Data entry locked.	System	12 Aug 2020 23:47:21
User entered '20 Nov 2020 23:59'	System	12 Aug 2020 23:47:21

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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 (85b2fbc9ef6e2e1b)', Time: '2020-11-24T16:32:45', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '35f92974-1aa1-4d69-815d-0e9540793b7f'	System	24 Nov 2020 22:33:21
User entered 'No (N)'	System	24 Nov 2020 22:33:21

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Have you been exposed to someone with known SARS-CoV-2 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 (85b2fbc9ef6e2e1b)', Time: '2020-11-24T16:33:00', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '35f92974-1aa1-4d69-815d-0e9540793b7f'	System	24 Nov 2020 22:33:21
User entered 'No (N)'	System	24 Nov 2020 22:33:21

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-11-24T16:33:14', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '35f92974-1aa1-4d69-815d-0e9540793b7f' User entered '24 Nov 2020 16:33:14'	System	24 Nov 2020 22:33:21

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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 (85b2fbc9ef6e2e1b)', Time: '2020-11-27T00:40:26', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '1a1a6134-cc0c-45ab-8f8a-4b68009c2e62'	System	27 Nov 2020 06:40:52
User entered 'No (N)'	System	27 Nov 2020 06:40:52

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you been exposed to someone with known SARS-CoV-2 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 (85b2fbc9ef6e2e1b)', Time: '2020-11-27T00:40:37', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '1a1a6134-cc0c-45ab-8f8a-4b68009c2e62'	System	27 Nov 2020 06:40:52
User entered 'No (N)'	System	27 Nov 2020 06:40:52

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-11-27T00:40:46', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '1a1a6134-cc0c-45ab-8f8a-4b68009c2e62'	System	27 Nov 2020 06:40:52
User entered '27 Nov 2020 00:40:46'	System	27 Nov 2020 06:40:52

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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 (85b2fbc9ef6e2e1b)', Time: '2020-12-06T19:16:12', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '409cdd7e-7291-4ff1-83ab-13f1d7da5014'	System	07 Dec 2020 01:16:31
User entered 'No (N)'	System	07 Dec 2020 01:16:31

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you been exposed to someone with known SARS-CoV-2 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 (85b2fbc9ef6e2e1b)', Time: '2020-12-06T19:16:18', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '409cdd7e-7291-4ff1-83ab-13f1d7da5014'	System	07 Dec 2020 01:16:31
User entered 'No (N)'	System	07 Dec 2020 01:16:31

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-12-06T19:16:24', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '409cdd7e-7291-4ff1-83ab-13f1d7da5014' User entered '06 Dec 2020 19:16:24'	System	07 Dec 2020 01:16:31
	System	07 Dec 2020 01:16:31

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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 (85b2fbc9ef6e2e1b)', Time: '2020-12-11T07:23:32', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '07286fa5-1c65-41b7-9b52-074f9bd7d0f1'	System	11 Dec 2020 13:23:54
User entered 'No (N)'	System	11 Dec 2020 13:23:54

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Have you been exposed to someone with known SARS-CoV-2 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 (85b2fbc9ef6e2e1b)', Time: '2020-12-11T07:23:37', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '07286fa5-1c65-41b7-9b52-074f9bd7d0f1'	System	11 Dec 2020 13:23:54
User entered 'No (N)'	System	11 Dec 2020 13:23:54

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-12-11T07:23:46', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '07286fa5-1c65-41b7-9b52-074f9bd7d0f1' User entered '11 Dec 2020 07:23:46'	System	11 Dec 2020 13:23:54
	System	11 Dec 2020 13:23:54

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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 (85b2fbc9ef6e2e1b)', Time: '2020-12-18T05:26:55', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '7bc14ac3-3ffd-4bb3-b763-ab9d5697ec84'	System	18 Dec 2020 11:27:50
User entered 'No (N)'	System	18 Dec 2020 11:27:50

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you been exposed to someone with known SARS-CoV-2 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 (85b2fbc9ef6e2e1b)', Time: '2020-12-18T05:26:58', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '7bc14ac3-3ffd-4bb3-b763-ab9d5697ec84'	System	18 Dec 2020 11:27:50
User entered 'No (N)'	System	18 Dec 2020 11:27:50

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-12-18T05:27:40', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '7bc14ac3-3ffd-4bb3-b763-ab9d5697ec84'	System	18 Dec 2020 11:27:50
User entered '18 Dec 2020 05:27:40'	System	18 Dec 2020 11:27:50

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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 (85b2fbc9ef6e2e1b)', Time: '2020-12-27T19:10:05', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '0788a025-10ef-4d36-9bdd-f72936f51d88'	System	28 Dec 2020 01:10:23
User entered 'No (N)'	System	28 Dec 2020 01:10:23

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you been exposed to someone with known SARS-CoV-2 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 (85b2fbc9ef6e2e1b)', Time: '2020-12-27T19:10:07', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '0788a025-10ef-4d36-9bdd-f72936f51d88'	System	28 Dec 2020 01:10:23
User entered 'No (N)'	System	28 Dec 2020 01:10:23

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2020-12-27T19:10:19', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '0788a025-10ef-4d36-9bdd-f72936f51d88'	System	28 Dec 2020 01:10:23
User entered '27 Dec 2020 19:10:19'	System	28 Dec 2020 01:10:23

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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 (85b2fbc9ef6e2e1b)', Time: '2021-01-05T10:57:14', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'd9a300bd-9e7d-4399-b41c-8a7d70d72d3a'	System	05 Jan 2021 16:57:56
User entered 'No (N)'	System	05 Jan 2021 16:57:56

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Have you been exposed to someone with known SARS-CoV-2 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 (85b2fbc9ef6e2e1b)', Time: '2021-01-05T10:57:29', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'd9a300bd-9e7d-4399-b41c-8a7d70d72d3a'	System	05 Jan 2021 16:57:56
User entered 'No (N)'	System	05 Jan 2021 16:57:56

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2021-01-05T10:57:47', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'd9a300bd-9e7d-4399-b41c-8a7d70d72d3a'	System	05 Jan 2021 16:57:56
User entered '05 Jan 2021 10:57:47'	System	05 Jan 2021 16:57:56

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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 (85b2fbc9ef6e2e1b)', Time: '2021-01-15T17:39:52', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '04a279c7-2bf8-4de3-a08e-77482473cb59'	System	15 Jan 2021 23:40:17
User entered 'No (N)'	System	15 Jan 2021 23:40:17

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you been exposed to someone with known SARS-CoV-2 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 (85b2fbc9ef6e2e1b)', Time: '2021-01-15T17:39:58', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '04a279c7-2bf8-4de3-a08e-77482473cb59'	System	15 Jan 2021 23:40:17
User entered 'No (N)'	System	15 Jan 2021 23:40:17

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2021-01-15T17:40:08', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '04a279c7-2bf8-4de3-a08e-77482473cb59'	System	15 Jan 2021 23:40:17
User entered '15 Jan 2021 17:40:08'	System	15 Jan 2021 23:40:17

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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 (85b2fbc9ef6e2e1b)', Time: '2021-01-22T07:25:16', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '2022a417-0c23-4650-be26-e5e9fbb230b6'	System	22 Jan 2021 13:25:36
User entered 'No (N)'	System	22 Jan 2021 13:25:36

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Have you been exposed to someone with known SARS-CoV-2 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 (85b2fbc9ef6e2e1b)', Time: '2021-01-22T07:25:19', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '2022a417-0c23-4650-be26-e5e9fbb230b6'	System	22 Jan 2021 13:25:36
User entered 'No (N)'	System	22 Jan 2021 13:25:36

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2021-01-22T07:25:29', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '2022a417-0c23-4650-be26-e5e9fbb230b6'	System	22 Jan 2021 13:25:36
User entered '22 Jan 2021 07:25:29'	System	22 Jan 2021 13:25:36

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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 (85b2fbc9ef6e2e1b)', Time: '2021-02-01T10:03:49', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'b0f2daa0-f562-445b-951d-bf735b63b249'	System	01 Feb 2021 16:04:13
User entered 'No (N)'	System	01 Feb 2021 16:04:13

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you been exposed to someone with known SARS-CoV-2 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 (85b2fbc9ef6e2e1b)', Time: '2021-02-01T10:03:56', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'b0f2daa0-f562-445b-951d-bf735b63b249'	System	01 Feb 2021 16:04:13
User entered 'No (N)'	System	01 Feb 2021 16:04:13

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2021-02-01T10:04:04', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'b0f2daa0-f562-445b-951d-bf735b63b249'	System	01 Feb 2021 16:04:13
User entered '01 Feb 2021 10:04:04'	System	01 Feb 2021 16:04:13

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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 (85b2fbc9ef6e2e1b)', Time: '2021-02-05T06:02:17', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '8cfcec16-7322-4766-ae32-d3f9ed55a831'	System	05 Feb 2021 12:02:49
User entered 'No (N)'	System	05 Feb 2021 12:02:49

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you been exposed to someone with known SARS-CoV-2 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 (85b2fbc9ef6e2e1b)', Time: '2021-02-05T06:02:21', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '8cfcec16-7322-4766-ae32-d3f9ed55a831'	System	05 Feb 2021 12:02:49
User entered 'No (N)'	System	05 Feb 2021 12:02:49

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2021-02-05T06:02:46', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '8cfcec16-7322-4766-ae32-d3f9ed55a831'	System	05 Feb 2021 12:02:49
User entered '05 Feb 2021 06:02:46'	System	05 Feb 2021 12:02:49

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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 (85b2fbc9ef6e2e1b)', Time: '2021-02-12T06:43:22', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '1fac7802-5a38-4fb6-9078-aaa693ff2382'	System	12 Feb 2021 12:43:38
User entered 'No (N)'	System	12 Feb 2021 12:43:38

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you been exposed to someone with known SARS-CoV-2 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 (85b2fbc9ef6e2e1b)', Time: '2021-02-12T06:43:25', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '1fac7802-5a38-4fb6-9078-aaa693ff2382'	System	12 Feb 2021 12:43:38
User entered 'No (N)'	System	12 Feb 2021 12:43:38

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2021-02-12T06:43:33', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '1fac7802-5a38-4fb6-9078-aaa693ff2382'	System	12 Feb 2021 12:43:38
User entered '12 Feb 2021 06:43:33'	System	12 Feb 2021 12:43:38

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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 (85b2fbc9ef6e2e1b)', Time: '2021-02-22T21:29:01-06:00', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '40ab9899-9332-42ea-a249-1d177cf51fc7'	System	23 Feb 2021 03:29:10
User entered 'No (N)'	System	23 Feb 2021 03:29:10

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Have you been exposed to someone with known SARS-CoV-2 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 (85b2fbc9ef6e2e1b)', Time: '2021-02-22T21:29:03-06:00', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '40ab9899-9332-42ea-a249-1d177cf51fc7'	System	23 Feb 2021 03:29:10
User entered 'No (N)'	System	23 Feb 2021 03:29:10

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2021-02-22T21:29:05-06:00', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '40ab9899-9332-42ea-a249-1d177cf51fc7'	System	23 Feb 2021 03:29:10
User entered '22 Feb 2021 21:29:05'	System	23 Feb 2021 03:29:10

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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 (85b2fbc9ef6e2e1b)', Time: '2021-03-05T06:30:43-06:00', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '251086d3-6301-42cc-a2ca-297596d7e780'	System	05 Mar 2021 12:30:58
User entered 'No (N)'	System	05 Mar 2021 12:30:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Have you been exposed to someone with known SARS-CoV-2 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 (85b2fbc9ef6e2e1b)', Time: '2021-03-05T06:30:46-06:00', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '251086d3-6301-42cc-a2ca-297596d7e780'	System	05 Mar 2021 12:30:58
User entered 'No (N)'	System	05 Mar 2021 12:30:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2021-03-05T06:30:51-06:00', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '251086d3-6301-42cc-a2ca-297596d7e780'	System	05 Mar 2021 12:30:58
User entered '05 Mar 2021 06:30:51'	System	05 Mar 2021 12:30:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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 (85b2fbc9ef6e2e1b)', Time: '2021-03-14T22:38:50-05:00', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '06cfdb17-73a9-44d0-9746-b1d14446ff39'	System	15 Mar 2021 03:39:05
User entered 'No (N)'	System	15 Mar 2021 03:39:05

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Have you been exposed to someone with known SARS-CoV-2 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 (85b2fbc9ef6e2e1b)', Time: '2021-03-14T22:38:53-05:00', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '06cfdb17-73a9-44d0-9746-b1d14446ff39'	System	15 Mar 2021 03:39:05
User entered 'No (N)'	System	15 Mar 2021 03:39:05

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2021-03-14T22:38:56-05:00', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '06cfdb17-73a9-44d0-9746-b1d14446ff39'	System	15 Mar 2021 03:39:05
User entered '14 Mar 2021 22:38:56'	System	15 Mar 2021 03:39:05

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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 (85b2fbc9ef6e2e1b)', Time: '2021-03-23T17:32:23-05:00', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '8bbf6e85-1d66-468a-a9df-7cb30c1366a4'	System	23 Mar 2021 22:32:41
User entered 'No (N)'	System	23 Mar 2021 22:32:41
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Have you been exposed to someone with known SARS-CoV-2 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 (85b2fbc9ef6e2e1b)', Time: '2021-03-23T17:32:31-05:00', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '8bbf6e85-1d66-468a-a9df-7cb30c1366a4'	System	23 Mar 2021 22:32:41
User entered 'No (N)'	System	23 Mar 2021 22:32:41
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2021-03-23T17:32:34-05:00', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '8bbf6e85-1d66-468a-a9df-7cb30c1366a4'	System	23 Mar 2021 22:32:41
User entered '23 Mar 2021 17:32:34'	System	23 Mar 2021 22:32:41
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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 (85b2fbc9ef6e2e1b)', Time: '2021-03-30T02:32:28-05:00', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '66788e76-453e-4c94-a936-b96f9af3e041'	System	30 Mar 2021 07:32:40
User entered 'No (N)'	System	30 Mar 2021 07:32:40
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you been exposed to someone with known SARS-CoV-2 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 (85b2fbc9ef6e2e1b)', Time: '2021-03-30T02:32:30-05:00', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '66788e76-453e-4c94-a936-b96f9af3e041'	System	30 Mar 2021 07:32:40
User entered 'No (N)'	System	30 Mar 2021 07:32:40
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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 (85b2fbc9ef6e2e1b)', Time: '2021-03-30T02:32:33-05:00', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '66788e76-453e-4c94-a936-b96f9af3e041'	System	30 Mar 2021 07:32:40
User entered '30 Mar 2021 02:32:33'	System	30 Mar 2021 07:32:40
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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 (85b2fbc9ef6e2e1b)', Time: '2021-04-02T00:03:37-05:00', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'b52fa495-5d65-45c8-92ac-87acd537b0f3'	System	02 Apr 2021 05:03:58
User entered 'No (N)'	System	02 Apr 2021 05:03:58
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you been exposed to someone with known SARS-CoV-2 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 (85b2fbc9ef6e2e1b)', Time: '2021-04-02T00:03:40-05:00', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'b52fa495-5d65-45c8-92ac-87acd537b0f3'	System	02 Apr 2021 05:03:58
User entered 'No (N)'	System	02 Apr 2021 05:03:58
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2021-04-02T00:03:48-05:00', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'b52fa495-5d65-45c8-92ac-87acd537b0f3'	System	02 Apr 2021 05:03:58
User entered '02 Apr 2021 00:03:48'	System	02 Apr 2021 05:03:58
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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 (85b2fbc9ef6e2e1b)', Time: '2021-04-09T00:56:24-05:00', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '78e8a1e9-4238-43f0-939a-1d702de2ccc9'	System	09 Apr 2021 05:56:39
User entered 'No (N)'	System	09 Apr 2021 05:56:39
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you been exposed to someone with known SARS-CoV-2 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 (85b2fbc9ef6e2e1b)', Time: '2021-04-09T00:56:28-05:00', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '78e8a1e9-4238-43f0-939a-1d702de2ccc9'	System	09 Apr 2021 05:56:39
User entered 'No (N)'	System	09 Apr 2021 05:56:39
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2021-04-09T00:56:32-05:00', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '78e8a1e9-4238-43f0-939a-1d702de2ccc9'	System	09 Apr 2021 05:56:39
User entered '09 Apr 2021 00:56:32'	System	09 Apr 2021 05:56:39
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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 (85b2fbc9ef6e2e1b)', Time: '2021-04-16T11:22:17-05:00', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '875adfa8-c2c0-47c7-8c04-6ece14075869'	System	16 Apr 2021 16:23:54
User entered 'No (N)'	System	16 Apr 2021 16:23:54
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you been exposed to someone with known SARS-CoV-2 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 (85b2fbc9ef6e2e1b)', Time: '2021-04-16T11:22:20-05:00', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '875adfa8-c2c0-47c7-8c04-6ece14075869'	System	16 Apr 2021 16:23:54
User entered 'No (N)'	System	16 Apr 2021 16:23:54
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2021-04-16T11:22:23-05:00', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: '875adfa8-c2c0-47c7-8c04-6ece14075869'	System	16 Apr 2021 16:23:54
User entered '16 Apr 2021 11:22:23'	System	16 Apr 2021 16:23:54
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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 (85b2fbc9ef6e2e1b)', Time: '2021-04-23T07:04:22-05:00', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'e1248a85-e56c-4130-85c1-3a5951f53b2a'	System	23 Apr 2021 12:04:45
User entered 'No (N)'	System	23 Apr 2021 12:04:45
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you been exposed to someone with known SARS-CoV-2 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 (85b2fbc9ef6e2e1b)', Time: '2021-04-23T07:04:25-05:00', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'e1248a85-e56c-4130-85c1-3a5951f53b2a'	System	23 Apr 2021 12:04:45
User entered 'No (N)'	System	23 Apr 2021 12:04:45
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2021-04-23T07:04:36-05:00', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'e1248a85-e56c-4130-85c1-3a5951f53b2a'	System	23 Apr 2021 12:04:45
User entered '23 Apr 2021 07:04:36'	System	23 Apr 2021 12:04:45
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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 (85b2fbc9ef6e2e1b)', Time: '2021-04-30T07:31:48-05:00', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'fd35a1f3-c332-43f1-bff2-475d4b795842'	System	30 Apr 2021 12:32:10
User entered 'No (N)'	System	30 Apr 2021 12:32:10
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you been exposed to someone with known SARS-CoV-2 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 (85b2fbc9ef6e2e1b)', Time: '2021-04-30T07:31:54-05:00', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'fd35a1f3-c332-43f1-bff2-475d4b795842'	System	30 Apr 2021 12:32:10
User entered 'No (N)'	System	30 Apr 2021 12:32:10
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2021-04-30T07:31:58-05:00', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'fd35a1f3-c332-43f1-bff2-475d4b795842'	System	30 Apr 2021 12:32:10
User entered '30 Apr 2021 07:31:58'	System	30 Apr 2021 12:32:10
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
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US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
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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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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DataPoint Activated.	System	22 Mar 2021 18:29:39
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US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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US3032201

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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	22 Mar 2021 18:29:39
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US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

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Folder: New Safety Follow Up Diary (1)

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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US3032201

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	22 Mar 2021 18:29:39
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US3032201

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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US3032201

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
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US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
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US3032201

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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)
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US3032201

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
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US3032201

Folder: New Safety Follow Up Diary (1)

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US3032201

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[Date and time of submission](#)

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US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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US3032201

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	22 Mar 2021 18:29:39
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US3032201

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	22 Mar 2021 18:29:39
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US3032201

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
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Folder: New Safety Follow Up Diary (1)

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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3032201

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
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US3032201

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	22 Mar 2021 18:29:39
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US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
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US3032201

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
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US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
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US3032201

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
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US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
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US3032201

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Form: Safety Follow Up Diary

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Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3032201

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
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US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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US3032201

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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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US3032201

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	22 Mar 2021 18:29:39
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US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3032201

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

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Folder: New Safety Follow Up Diary (1)

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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
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US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
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US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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[Date and time of submission](#)

Audit	User	Time (GMT)
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US3032201

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
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US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
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Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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

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DataPoint Activated.	System	22 Mar 2021 18:29:39
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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3032201

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
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US3032201

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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US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
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Folder: New Safety Follow Up Diary (1)

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US3032201

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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

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DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

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DataPoint Activated.	System	22 Mar 2021 18:29:39
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US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
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Folder: New Safety Follow Up Diary (1)

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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
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US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
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US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

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Folder: New Safety Follow Up Diary (1)

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US3032201

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

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US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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DataPoint Activated.	System	22 Mar 2021 18:29:39
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US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
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US3032201

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

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Folder: New Safety Follow Up Diary (1)

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DataPoint Activated.	System	22 Mar 2021 18:29:39
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US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
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US3032201

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3032201

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
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US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3032201

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Audit	User	Time (GMT)
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US3032201

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
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US3032201

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
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US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
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US3032201

Folder: New Safety Follow Up Diary (1)

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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
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US3032201

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3032201

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
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US3032201

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
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US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

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Folder: New Safety Follow Up Diary (1)

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US3032201

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

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Folder: New Safety Follow Up Diary (1)

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US3032201

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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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US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
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US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
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US3032201

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
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US3032201

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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DataPoint Activated.	System	22 Mar 2021 18:29:39
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US3032201

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
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US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3032201

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 05:36:58

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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Audit	User	Time (GMT)
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US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
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US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
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US3032201

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

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

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
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US3032201

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
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DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:09

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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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
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US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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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US3032201

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	22 Mar 2021 18:29:39
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US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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[Runny nose](#)

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DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

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Folder: New Safety Follow Up Diary (1)

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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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US3032201

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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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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
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US3032201

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
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US3032201

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
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US3032201

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 21:52:11

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
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US3032201

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
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US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 21:52:11

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
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US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
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US3032201

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
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US3032201

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
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US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
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US3032201

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
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US3032201

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
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US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
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US3032201

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	22 Mar 2021 18:29:39
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Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

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DataPoint Activated.	System	22 Mar 2021 18:29:39
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US3032201

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3032201

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
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US3032201

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	22 Mar 2021 18:29:39
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US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

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Folder: New Safety Follow Up Diary (1)

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US3032201

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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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US3032201

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Audit	User	Time (GMT)
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DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Have you had 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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

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	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 05:36:58

US3032201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	22 Mar 2021 18:29:39
DataPoint Inactivated.	System	22 Mar 2021 18:29:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:36:58
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 05:36:58

US3032201

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 21:52:11

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:20:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2021-03-03T07:18:54-06:00', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'c3e45c23-d6c9-4c96-a653-ae362dfe292'	System	03 Mar 2021 13:19:08
User entered 'No (N)'	System	03 Mar 2021 13:19:08

US3032201

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 21:52:11

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:20:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85b2fbc9ef6e2e1b)', Time: '2021-03-03T07:18:59-06:00', User OID: 'PatientReportedOutcome (US3032201)', ODM File OID: 'c3e45c23-d6c9-4c96-a653-ae362dafa292'	System	03 Mar 2021 13:19:08
User entered '03 Mar 2021 07:18:59'	System	03 Mar 2021 13:19:08

US3032201

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:43
User entered 'Yes (Y)'	(b) (4) Russell Herstein (b) (4) (b) (4)	10 Nov 2020 14:02:12

US3032201

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:43
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	23 Nov 2020 15:48:02
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	23 Nov 2020 15:48:02
User entered '02 Nov 2020' reason for change: Data Entry Error	Linden DeBoer (b) (4)	23 Nov 2020 15:48:02
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	10 Nov 2020 14:02:12
User entered '09 Nov 2020'	System	10 Nov 2020 14:02:12
	Russell Herstein (b) (4)	10 Nov 2020 14:02:12
	(b) (4)	

US3032201

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Russell Herstein (b) (4)	10 Nov 2020 14:02:12

US3032201

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:43
User entered empty.	(b) (4) Russell Herstein (b) (4)	10 Nov 2020 14:02:12

US3032201

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	10 Nov 2020 21:37:10
User entered 'Yes (Y)'	(b) (4) Russell Herstein (b) (4)	10 Nov 2020 14:02:16

US3032201

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:40
User entered 'I'	System	10 Nov 2020 14:02:16

US3032201

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:00:38
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:32
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Dec 2020 21:02:30

US3032201

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:00:38
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:32
User entered '25 Nov 2020'	(b) (4) Kelsey Kelley (b) (4)	22 Dec 2020 21:02:30

US3032201

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:00:38
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4)	22 Dec 2020 21:02:30

US3032201

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:00:38
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Dec 2020 21:02:30

US3032201

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:00:38
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:32
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Dec 2020 21:02:36

US3032201

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:00:38
User entered 'I'	System	22 Dec 2020 21:02:36

US3032201

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:00:38
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:22
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	13 Jan 2021 00:33:57

US3032201

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:00:38
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:22
User entered '5 Jan 2021'	(b) (4) Kelsey Kelley (b) (4)	13 Jan 2021 00:33:57

US3032201

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:00:38
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4)	13 Jan 2021 00:33:57

US3032201

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:00:38
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:22
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	13 Jan 2021 00:33:57

US3032201

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:00:38
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:22
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	13 Jan 2021 00:34:01

US3032201

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:00:38
User entered '1'	System	13 Jan 2021 00:34:01

US3032201

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:29
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:04
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	05 Feb 2021 22:20:05

US3032201

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:29
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	22 Mar 2021 18:29:39
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	22 Mar 2021 18:29:09
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:04
User entered '5 Feb 2021'	Kelsey Kelley (b) (4)	05 Feb 2021 22:20:05

US3032201

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:29
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4)	05 Feb 2021 22:20:05

US3032201

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:29
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:04
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	05 Feb 2021 22:20:05

US3032201

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:00:38
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:04
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	05 Feb 2021 22:20:08

US3032201

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:00:38
User entered '1'	System	05 Feb 2021 22:20:08

US3032201

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:29
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:06:26

US3032201

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:11

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:29
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 01:36:43
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'Correct as entered, subject had rescheduled due to personal reasons involving AE of pregnancy' (Site from System).	Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 16:06:56
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	25 Mar 2021 16:06:26
User entered '25 Mar 2021'	Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 16:06:26

US3032201

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:11

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:29
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 16:06:26

US3032201

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:29
User entered 'VISIT4'	System	25 Mar 2021 16:06:26

US3032201

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:29
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
User entered 'No (N)'	Samantha Wieseler (b) (4)	30 Mar 2021 21:27:17

US3032201

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:29
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
User entered empty.	Samantha Wieseler (b) (4)	30 Mar 2021 21:27:17

US3032201

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:29
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
User entered empty.	Samantha Wieseler (b) (4)	30 Mar 2021 21:27:17

US3032201

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:29
User entered empty.	System	30 Mar 2021 21:27:17

US3032201

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:29
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	30 Mar 2021 21:27:17

US3032201

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:29
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	30 Mar 2021 21:27:17

US3032201

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:29
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	30 Mar 2021 21:27:17

US3032201

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:29
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
User entered empty.	Samantha Wieseler (b) (4)	30 Mar 2021 21:27:17

US3032201

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:29
User entered empty.	System	30 Mar 2021 21:27:17

US3032201

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:29
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
User entered empty.	Samantha Wieseler (b) (4)	30 Mar 2021 21:27:17

US3032201

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:29
User entered empty.	System	30 Mar 2021 21:27:17

US3032201

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:29
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	30 Mar 2021 21:27:17

US3032201

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:29
User entered empty.	System	30 Mar 2021 21:27:17

US3032201

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:29
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
User entered empty.	Samantha Wieseler (b) (4)	30 Mar 2021 21:27:17

US3032201

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:29
User entered empty.	System	30 Mar 2021 21:27:17

US3032201

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:29

US3032201

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:29

US3032201

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:29
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:07:17

US3032201

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:29
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
User entered '25 Mar 2021'	Kelsey Kelley (b) (4)	25 Mar 2021 16:07:17

US3032201

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:29
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:07:26

US3032201

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:29
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
User entered '25 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:07:26
	(b) (4)	

US3032201

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:11

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:29
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
User entered '09:15'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:07:26

US3032201

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:29
User entered '25 Mar 2021 09:15'	System	25 Mar 2021 16:07:26

US3032201

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:29
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:07:28

US3032201

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:29
User entered 'I'	System	25 Mar 2021 16:07:28

US3032201

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:59
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:28
User entered 'Yes (Y)'	Chelsie Nutsch (b) (4)	06 Apr 2021 19:32:24

US3032201

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:59
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:28
User entered '6 Apr 2021'	Chelsie Nutsch (b) (4)	06 Apr 2021 19:32:24

US3032201

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:59
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:28
User entered 'Contact Made (CONTACT MADE)'	Chelsie Nutsch (b) (4)	06 Apr 2021 19:32:24

US3032201

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:59
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:28
User entered empty.	(b) (4) Chelsie Nutsch (b) (4)	06 Apr 2021 19:32:24

US3032201

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:59
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:28
User entered 'Yes (Y)'	Chelsie Nutsch (b) (4)	06 Apr 2021 19:32:27

US3032201

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:59
User entered '1'	System	06 Apr 2021 19:32:27

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	21 Jan 2021 19:46:44

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:11

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered '21 Jan 2021'	Kelsey Kelley (b) (4)	21 Jan 2021 19:46:44

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:11

[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 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered 'Clinic (Clinic)'	Kelsey Kelley (b) (4)	21 Jan 2021 19:46:44

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered 'UNBLND_DECIDE'	System	21 Jan 2021 19:46:44

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:52:11

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered '21 Jan 2021'	Kelsey Kelley (b) (4)	21 Jan 2021 19:47:04

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:52:11

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:15:39
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:26:20

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:52:11

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	21 Jan 2021 19:47:04

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:52:11

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:15:39
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:26:20

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:52:11

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered '21 Jan 2021'	Kelsey Kelley (b) (4)	21 Jan 2021 19:47:04

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:52:11

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered 'Placebo (Placebo)'	Kelsey Kelley (b) (4)	21 Jan 2021 19:47:04

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:52:11

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered 'Placebo (Placebo)'	Kelsey Kelley (b) (4)	21 Jan 2021 19:47:04

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:52:11

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered 'Placebo (Placebo)'	Kelsey Kelley (b) (4)	21 Jan 2021 19:47:04

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:52:11

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	21 Jan 2021 19:47:04

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:52:11

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered 'I'	System	21 Jan 2021 19:47:04

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:52:11

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered 'I'	System	21 Jan 2021 19:47:04

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered missing code ND - Not Done.	Kelsey Kelley (b) (4)	21 Jan 2021 19:49:24

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered missing code ND - Not Done.	Kelsey Kelley (b) (4)	21 Jan 2021 19:49:24

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered empty.	System	21 Jan 2021 19:49:24
DataPoint set to visible.	System	21 Jan 2021 19:47:04

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered missing code ND - Not Done.	Kelsey Kelley (b) (4)	21 Jan 2021 19:49:24

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered missing code ND - Not Done.	Kelsey Kelley (b) (4)	21 Jan 2021 19:49:24

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered empty.	System	21 Jan 2021 19:49:24
DataPoint set to visible.	System	21 Jan 2021 19:47:04

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	21 Jan 2021 19:49:24

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	21 Jan 2021 19:49:24

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered '21 Jan 2021'	Kelsey Kelley (b) (4)	21 Jan 2021 19:49:24

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered '11:05'	Kelsey Kelley (b) (4)	21 Jan 2021 19:49:24

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered '21 Jan 2021 11:05'	System	21 Jan 2021 19:49:24

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered '36.5' C	Kelsey Kelley (b) (4)	21 Jan 2021 19:49:24

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered 'Oral (Oral)'	Kelsey Kelley (b) (4)	21 Jan 2021 19:49:24

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	21 Jan 2021 19:49:24

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered '79'	Kelsey Kelley (b) (4)	21 Jan 2021 19:49:24

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered 'bpm'	System	21 Jan 2021 19:49:24

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered '15'	Kelsey Kelley (b) (4)	21 Jan 2021 19:49:24

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered 'breaths/min'	System	21 Jan 2021 19:49:24

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered '120'	Kelsey Kelley (b) (4)	21 Jan 2021 19:49:24

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered 'mmHg'	System	21 Jan 2021 19:49:24

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered '88'	Kelsey Kelley (b) (4)	21 Jan 2021 19:49:24

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered 'mmHg'	System	21 Jan 2021 19:49:24

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered missing code ND - Not Done.	Kelsey Kelley (b) (4)	21 Jan 2021 19:49:24

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered missing code ND - Not Done.	Kelsey Kelley (b) (4)	21 Jan 2021 19:49:24

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered empty.	System	21 Jan 2021 19:49:24
DataPoint set to visible.	System	21 Jan 2021 19:47:04

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	21 Jan 2021 19:49:47

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	21 Jan 2021 19:49:47

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered '21 Jan 2021'	Kelsey Kelley (b) (4)	21 Jan 2021 19:49:47

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered '12:13'	Kelsey Kelley (b) (4)	21 Jan 2021 19:49:47

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered '21 Jan 2021 12:13'	System	21 Jan 2021 19:49:47

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered '36.7' C	Kelsey Kelley (b) (4)	21 Jan 2021 19:49:47

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	21 Jan 2021 19:49:47
	(b) (4)	

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	21 Jan 2021 19:49:47

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered '79'	Kelsey Kelley (b) (4)	21 Jan 2021 19:49:47

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered 'bpm'	System	21 Jan 2021 19:49:47

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered '14'	Kelsey Kelley (b) (4)	21 Jan 2021 19:49:47

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered 'breaths/min'	System	21 Jan 2021 19:49:47

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered '121'	(b) (4) Kelsey Kelley (b) (4)	21 Jan 2021 19:49:47

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered 'mmHg'	System	21 Jan 2021 19:49:47

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered '86'	Kelsey Kelley (b) (4)	21 Jan 2021 19:49:47

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered 'mmHg'	System	21 Jan 2021 19:49:47

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	21 Jan 2021 19:47:39

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered '21 Jan 2021'	Kelsey Kelley (b) (4)	21 Jan 2021 19:47:39

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	21 Jan 2021 19:48:50

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered '21 Jan 2021'	Kelsey Kelley (b) (4)	21 Jan 2021 19:48:50

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered 'Urine (URINE)'	Kelsey Kelley (b) (4)	21 Jan 2021 19:48:50

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered 'Negative (NEGATIVE)'	(b) (4) Kelsey Kelley (b) (4)	21 Jan 2021 19:48:50

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered 'No (N)'	Kelsey Kelley (b) (4)	21 Jan 2021 19:48:50

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	21 Jan 2021 19:48:50

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	21 Jan 2021 19:48:50

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered empty.	System	21 Jan 2021 19:48:50

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	21 Jan 2021 19:48:14

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered empty.	Kelsey Kelley (b) (4)	21 Jan 2021 19:48:14

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered empty.	Kelsey Kelley (b) (4)	21 Jan 2021 19:48:14

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered 'mRNA-1273'	System	21 Jan 2021 19:48:14
DataPoint set to visible.	System	21 Jan 2021 19:47:04

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered '21 Jan 2021'	Kelsey Kelley (b) (4)	21 Jan 2021 19:48:14

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered '11:39'	Kelsey Kelley (b) (4)	21 Jan 2021 19:48:14

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered '21 Jan 2021 11:39'	System	21 Jan 2021 19:48:14

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered 'Left Arm (LEFT ARM)'	Kelsey Kelley (b) (4)	21 Jan 2021 19:48:14

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered 'ONCE'	System	21 Jan 2021 19:48:14

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered 'INTRAMUSCULAR'	System	21 Jan 2021 19:48:14

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	21 Jan 2021 19:47:20

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered '21 Jan 2021'	Kelsey Kelley (b) (4)	21 Jan 2021 19:47:20

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:11

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered '10:41'	Kelsey Kelley (b) (4)	21 Jan 2021 19:47:20

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered '21 Jan 2021 10:41'	System	21 Jan 2021 19:47:20

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:52:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	21 Jan 2021 19:47:29

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:52:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered '21 Jan 2021'	Kelsey Kelley (b) (4)	21 Jan 2021 19:47:29

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:52:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered '10:46'	Kelsey Kelley (b) (4)	21 Jan 2021 19:47:29

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:52:11

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered '21 Jan 2021 10:46'	System	21 Jan 2021 19:47:29

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:59
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	21 Jan 2021 19:47:31

US3032201

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:02
User entered 'I'	System	21 Jan 2021 19:47:31

US3032201

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:28
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Feb 2021 15:26:57

US3032201

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:28
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered '28 Jan 2021'	Kelsey Kelley (b) (4)	19 Feb 2021 15:26:57

US3032201

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:28
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'Contact Made (CONTACT MADE)'	Kelsey Kelley (b) (4)	19 Feb 2021 15:26:57

US3032201

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:28
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Feb 2021 15:26:57

US3032201

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:28
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	19 Feb 2021 15:25:36

US3032201

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:28
User entered 'I'	System	19 Feb 2021 15:25:36

US3032201

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:28
User entered '1'	System	19 Feb 2021 15:25:36
DataPoint set to visible.	System	19 Feb 2021 15:25:36

US3032201

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 15:27:17

US3032201

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:11

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User closed query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	22 Mar 2021 18:29:39
User opened query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	22 Mar 2021 18:29:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered '18 Feb 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Feb 2021 15:27:17

US3032201

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:11

[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 18:52:26
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'Clinic (Clinic)'	Kelsey Kelley (b) (4)	19 Feb 2021 15:27:17

US3032201

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User entered 'OLD29'	System	19 Feb 2021 15:27:17

US3032201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	19 Feb 2021 15:29:59

US3032201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 15:29:59

US3032201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User closed query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	22 Mar 2021 18:29:39
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	22 Mar 2021 18:29:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered '18 Feb 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Feb 2021 15:29:59

US3032201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered '14:36'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Feb 2021 15:29:59

US3032201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User entered '18 Feb 2021 14:36'	System	19 Feb 2021 15:29:59

US3032201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered '36.5' C	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 15:29:59
	(b) (4)	

US3032201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 15:29:59
	(b) (4)	

US3032201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 15:29:59
	(b) (4)	

US3032201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered '88'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 15:29:59

US3032201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User entered 'bpm'	System	19 Feb 2021 15:29:59

US3032201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered '15'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 15:29:59

US3032201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User entered 'breaths/min'	System	19 Feb 2021 15:29:59

US3032201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered '124'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 15:29:59
	(b) (4)	

US3032201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User entered 'mmHg'	System	19 Feb 2021 15:29:59

US3032201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered '78'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 15:29:59

US3032201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User entered 'mmHg'	System	19 Feb 2021 15:29:59

US3032201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	19 Feb 2021 15:30:10

US3032201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 15:30:10
	(b) (4)	

US3032201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered empty.	Kelsey Kelley (b) (4)	19 Feb 2021 15:30:10

US3032201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 15:30:10
	(b) (4)	

US3032201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User entered empty.	System	19 Feb 2021 15:30:10

US3032201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 15:30:10
	(b) (4)	

US3032201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 15:30:10
	(b) (4)	

US3032201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 15:30:10
	(b) (4)	

US3032201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 15:30:10
	(b) (4)	

US3032201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User entered empty.	System	19 Feb 2021 15:30:10

US3032201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 15:30:10
	(b) (4)	

US3032201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User entered empty.	System	19 Feb 2021 15:30:10

US3032201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 15:30:10
	(b) (4)	

US3032201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User entered empty.	System	19 Feb 2021 15:30:10

US3032201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 15:30:10

US3032201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User entered empty.	System	19 Feb 2021 15:30:10

US3032201

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 15:29:08

US3032201

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User closed query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).		22 Mar 2021 18:29:39
User opened query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).		22 Mar 2021 18:29:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered '18 Feb 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Feb 2021 15:29:08

US3032201

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 15:27:45

US3032201

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User closed query 'Date of Test 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	22 Mar 2021 18:29:39
User opened query 'Date of Test 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	22 Mar 2021 18:29:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered '18 Feb 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Feb 2021 15:27:45

US3032201

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'Urine (URINE)'	Kelsey Kelley (b) (4)	19 Feb 2021 15:27:45

US3032201

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User closed query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' (Site from System). User signature succeeded.	(b) (4)	23 Feb 2021 06:43:24
Query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' answered with 'pregnancy form has been submitted to IQVIA' (Site from System).	Keith Vrbicky (b) (4) (b) (4)	22 Feb 2021 17:25:31
User opened query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' (Site from System). User entered 'Positive (POSITIVE)'	Samantha Wieseler (b) (4) (b) (4)	19 Feb 2021 18:04:00
	System	19 Feb 2021 15:27:45
	Kelsey Kelley (b) (4) (b) (4)	19 Feb 2021 15:27:45

US3032201

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 15:27:45

US3032201

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 15:27:45

US3032201

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 15:27:45

US3032201

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User entered empty.	System	19 Feb 2021 15:27:45

US3032201

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User closed query 'Was study treatment given is "Yes", however Pregnancy Form indicates subject has positive results. Please review and update or explain otherwise.' (Site from System).	(b) (4), (b) (6)	28 Apr 2021 06:20:07
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:40
Query 'Was study treatment given is "Yes", however Pregnancy Form indicates subject had positive results. Please review and update or explain otherwise.' answered with 'subject was dosed at a later date. please see unscheduled #1' (Site from System).	Samantha Wieseler (b) (4)	16 Apr 2021 22:02:05
User opened query 'Was study treatment given is "Yes", however Pregnancy Form indicates subject had positive results. Please review and update or explain otherwise.' (Site from System).	System	16 Apr 2021 22:01:36
Signature has been broken.	Samantha Wieseler (b) (4)	16 Apr 2021 22:01:36
User entered 'Yes (Y)' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	16 Apr 2021 22:01:36
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'No (N)'	Kelsey Kelley (b) (4)	19 Feb 2021 15:28:19

US3032201

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:40
Signature has been broken.	Samantha Wieseler (b) (4)	16 Apr 2021 22:01:36
User entered empty; reason for change Data Entry Error	Samantha Wieseler (b) (4)	16 Apr 2021 22:01:36
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'Pregnancy (PREGNANCY)'	Kelsey Kelley (b) (4)	19 Feb 2021 15:28:19

US3032201

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

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 Apr 2021 18:52:26
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered empty.	Kelsey Kelley (b) (4)	19 Feb 2021 15:28:19

US3032201

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User entered 'mRNA-1273'	System	16 Apr 2021 22:01:36
User entered empty.	System	19 Feb 2021 15:28:19
DataPoint set to visible.	System	19 Feb 2021 15:25:36

US3032201

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	28 Apr 2021 06:20:16
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:40
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered with 'subject was dosed at a later date. please see unscheduled #1' (Site from System).	(b) (4)	
	Samantha Wieseler (b) (4)	16 Apr 2021 22:02:07
	(b) (4)	
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	16 Apr 2021 22:01:36
Signature has been broken.	Samantha Wieseler (b) (4)	16 Apr 2021 22:01:36
	(b) (4)	
User entered '16 Apr 2021' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	16 Apr 2021 22:01:36
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	19 Feb 2021 15:28:19
	(b) (4)	

US3032201

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:40
Signature has been broken.	Samantha Wieseler (b) (4)	16 Apr 2021 22:01:36
User entered '11:39' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	16 Apr 2021 22:01:36
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered empty.	Kelsey Kelley (b) (4)	19 Feb 2021 15:28:19

US3032201

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User entered '16 Apr 2021 11:39'	System	16 Apr 2021 22:01:36
User entered empty.	System	19 Feb 2021 15:28:19

US3032201

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:40
Signature has been broken.	Samantha Wieseler (b) (4)	16 Apr 2021 22:01:36
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	16 Apr 2021 22:01:36
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered empty.	Kelsey Kelley (b) (4)	19 Feb 2021 15:28:19

US3032201

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User entered 'ONCE'	System	16 Apr 2021 22:01:36
User entered empty.	System	19 Feb 2021 15:28:19

US3032201

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:11

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User entered 'INTRAMUSCULAR'	System	16 Apr 2021 22:01:36
User entered empty.	System	19 Feb 2021 15:28:19

US3032201

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	19 Feb 2021 15:28:26

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Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:26
User entered 'I'	System	19 Feb 2021 15:28:26

US3032201

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:28
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:15:39
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	(b) (4) System	15 Mar 2021 22:16:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	15 Mar 2021 22:16:55
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	15 Mar 2021 22:16:18
User entered 'No (N)' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	15 Mar 2021 22:16:18
User entered 'Yes (Y)'	Linden DeBoer (b) (4) (b) (4)	12 Mar 2021 19:50:28

US3032201

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:28
User signature succeeded.	Keith Vrbicky (b) (4)	23 Apr 2021 19:37:17
Signature has been broken.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 14:13:20
User entered '23 Apr 2021' reason for change: Data Entry Error		23 Apr 2021 14:13:20
User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		21 Apr 2021 01:15:42
Query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'call will be updated once it comes time to make this call following new OL2 visit.' (Site from System).	Samantha Wieseler (b) (4)	19 Apr 2021 13:53:30
User opened query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	16 Apr 2021 22:01:36
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	22 Mar 2021 18:29:39
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	22 Mar 2021 18:29:09
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:15:39
User entered '25 Feb 2021' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	15 Mar 2021 22:16:55
User entered empty; reason for change Data Entry Error	Samantha Wieseler (b) (4)	15 Mar 2021 22:16:18

US3032201

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '25 Feb 2021'	Linden DeBoer (b) (4) (b) (4)	12 Mar 2021 19:50:28

US3032201

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:28
User signature succeeded.	Keith Vrbicky (b) (4)	23 Apr 2021 19:37:17
Signature has been broken.	(b) (4) (U), (4), (b) (6)	23 Apr 2021 14:13:20
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information		23 Apr 2021 14:13:20
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:15:39
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	(b) (4) Samantha Wieseler (b) (4)	15 Mar 2021 22:16:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Linden DeBoer (b) (4)	12 Mar 2021 19:50:28
	(b) (4)	

US3032201

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:28
User signature succeeded.	Keith Vrbicky (b) (4)	23 Apr 2021 19:37:17
Signature has been broken.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:13:20
User entered empty; reason for change New Information		23 Apr 2021 14:13:20
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:29
Signature has been broken.	(b) (4) Chelsie Nutsch (b) (4)	09 Apr 2021 14:42:26
User entered 'CALL WAS NOT ATTEMPTED DUE TO SUBJECT not RECEIVING 2ND DOSE OF VACCINE DUE TO PREGNANCY.' reason for change: Data Entry Error	(b) (4) Chelsie Nutsch (b) (4)	09 Apr 2021 14:42:26
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:15:39
User entered 'call was not attempted due to subject to Samantha Wieseler receiving 2nd dose of vaccine due to pregnancy.' reason for change: Data Entry Error	(b) (4) (b) (4)	15 Mar 2021 22:16:18
User entered empty.	Linden DeBoer (b) (4)	12 Mar 2021 19:50:28
	(b) (4)	

US3032201

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:28
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:15:39
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	12 Mar 2021 19:50:56

US3032201

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:28
User entered 'I'	System	12 Mar 2021 19:50:56

US3032201

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	31 Mar 2021 17:06:12
	(b) (4)	

US3032201

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:11

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	21 Apr 2021 01:06:23
Query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' answered with 'Date is correct as entered. Subject had OL3 after original OL2. following this OL2 will be put in as an unscheduled visit. ' (Site from System).	Samantha Wieseler (b) (4)	19 Apr 2021 13:52:22
User opened query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	16 Apr 2021 22:01:36
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
User entered '30 Mar 2021'	Kelsey Kelley (b) (4)	31 Mar 2021 17:06:12

US3032201

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:11

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
	(b) (4)	
User entered 'Clinic (Clinic)'	Kelsey Kelley (b) (4)	31 Mar 2021 17:06:12
	(b) (4)	

US3032201

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:11

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	31 Mar 2021 17:06:12

US3032201

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	31 Mar 2021 17:06:34
	(b) (4)	

US3032201

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
	(b) (4)	
User entered '30 Mar 2021'	Kelsey Kelley (b) (4)	31 Mar 2021 17:06:34
	(b) (4)	

US3032201

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
	(b) (4)	
User entered '09:59'	Kelsey Kelley (b) (4)	31 Mar 2021 17:06:34
	(b) (4)	

US3032201

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 09:59'	System	31 Mar 2021 17:06:34

US3032201

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
	(b) (4)	
User entered '36.7' C	Kelsey Kelley (b) (4)	31 Mar 2021 17:06:34
	(b) (4)	

US3032201

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
	(b) (4)	
User entered 'Oral (Oral)'	Kelsey Kelley (b) (4)	31 Mar 2021 17:06:34
	(b) (4)	

US3032201

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	31 Mar 2021 17:06:34
	(b) (4)	

US3032201

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
	(b) (4)	
User entered '79'	Kelsey Kelley (b) (4)	31 Mar 2021 17:06:34
	(b) (4)	

US3032201

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	31 Mar 2021 17:06:34

US3032201

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
	(b) (4)	
User entered '16'	Kelsey Kelley (b) (4)	31 Mar 2021 17:06:34
	(b) (4)	

US3032201

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	31 Mar 2021 17:06:34

US3032201

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
User entered '124'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	31 Mar 2021 17:06:34

US3032201

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Mar 2021 17:06:34

US3032201

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
	(b) (4)	
User entered '87'	Kelsey Kelley (b) (4)	31 Mar 2021 17:06:34
	(b) (4)	

US3032201

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Mar 2021 17:06:34

US3032201

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	31 Mar 2021 17:06:40
	(b) (4)	

US3032201

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	31 Mar 2021 17:06:40
	(b) (4)	

US3032201

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	31 Mar 2021 17:06:55
	(b) (4)	

US3032201

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
	(b) (4)	
User entered '30 Mar 2021'	Kelsey Kelley (b) (4)	31 Mar 2021 17:06:55
	(b) (4)	

US3032201

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:11

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
	(b) (4)	
User entered '10:04'	Kelsey Kelley (b) (4)	31 Mar 2021 17:06:55
	(b) (4)	

US3032201

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 10:04'	System	31 Mar 2021 17:06:55

US3032201

Folder: Unscheduled 16 Apr 2021

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 21:52:11

[Visit Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:40
	(b) (4)	
User entered '16 Apr 2021'	Samantha Wieseler (b) (4)	16 Apr 2021 21:59:22
	(b) (4)	

US3032201

Folder: Unscheduled 16 Apr 2021

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 21:52:11

[Physical Exam](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:40
	(b) (4)	
User entered 'I'	Samantha Wieseler (b) (4)	16 Apr 2021 21:59:22
	(b) (4)	

US3032201

Folder: Unscheduled 16 Apr 2021

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 21:52:11

[Vital Signs](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:40
	(b) (4)	
User entered '1'	Samantha Wieseler (b) (4)	16 Apr 2021 21:59:22
	(b) (4)	

US3032201

Folder: Unscheduled 16 Apr 2021

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 21:52:11

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:40
	(b) (4)	
User entered 'I'	Samantha Wieseler (b) (4)	16 Apr 2021 21:59:22
	(b) (4)	

US3032201

Folder: Unscheduled 16 Apr 2021

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 21:52:11

[Pregnancy Test](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:40
	(b) (4)	
User entered 'I'	Samantha Wieseler (b) (4)	16 Apr 2021 21:59:22
	(b) (4)	

US3032201

Folder: Unscheduled 16 Apr 2021

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:40
	(b) (4)	
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	16 Apr 2021 21:59:54
	(b) (4)	

US3032201

Folder: Unscheduled 16 Apr 2021

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:40
	(b) (4)	
User entered '16 Apr 2021'	Samantha Wieseler (b) (4)	16 Apr 2021 21:59:54
	(b) (4)	

US3032201

Folder: Unscheduled 16 Apr 2021

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:40
	(b) (4)	
User entered '10:33'	Samantha Wieseler (b) (4)	16 Apr 2021 21:59:54
	(b) (4)	

US3032201

Folder: Unscheduled 16 Apr 2021

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '16 Apr 2021 10:33'	System	16 Apr 2021 21:59:54

US3032201

Folder: Unscheduled 16 Apr 2021

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:40
	(b) (4)	
User entered '36.9' C	Samantha Wieseler (b) (4)	16 Apr 2021 21:59:54
	(b) (4)	

US3032201

Folder: Unscheduled 16 Apr 2021

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:40
	(b) (4)	
User entered 'Oral (Oral)'	Samantha Wieseler (b) (4)	16 Apr 2021 21:59:54
	(b) (4)	

US3032201

Folder: Unscheduled 16 Apr 2021

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:40
	(b) (4)	
User entered empty.	Samantha Wieseler (b) (4)	16 Apr 2021 21:59:54
	(b) (4)	

US3032201

Folder: Unscheduled 16 Apr 2021

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:40
	(b) (4)	
User entered '77'	Samantha Wieseler (b) (4)	16 Apr 2021 21:59:54
	(b) (4)	

US3032201

Folder: Unscheduled 16 Apr 2021

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	16 Apr 2021 21:59:54

US3032201

Folder: Unscheduled 16 Apr 2021

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:40
	(b) (4)	
User entered '18'	Samantha Wieseler (b) (4)	16 Apr 2021 21:59:54
	(b) (4)	

US3032201

Folder: Unscheduled 16 Apr 2021

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	16 Apr 2021 21:59:54

US3032201

Folder: Unscheduled 16 Apr 2021

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:40
	(b) (4)	
User entered '140'	Samantha Wieseler (b) (4)	16 Apr 2021 21:59:54
	(b) (4)	

US3032201

Folder: Unscheduled 16 Apr 2021

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Apr 2021 21:59:54

US3032201

Folder: Unscheduled 16 Apr 2021

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:40
	(b) (4)	
User entered '90'	Samantha Wieseler (b) (4)	16 Apr 2021 21:59:54
	(b) (4)	

US3032201

Folder: Unscheduled 16 Apr 2021

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Apr 2021 21:59:54

US3032201

Folder: Unscheduled 16 Apr 2021

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:40
	(b) (4)	
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	16 Apr 2021 22:00:01
	(b) (4)	

US3032201

Folder: Unscheduled 16 Apr 2021

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:40
	(b) (4)	
User entered '16 Apr 2021'	Samantha Wieseler (b) (4)	16 Apr 2021 22:00:01
	(b) (4)	

US3032201

Folder: Unscheduled 16 Apr 2021

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:40
	(b) (4)	
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	16 Apr 2021 22:00:33
	(b) (4)	

US3032201

Folder: Unscheduled 16 Apr 2021

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:40
	(b) (4)	
User entered '16 Apr 2021'	Samantha Wieseler (b) (4)	16 Apr 2021 22:00:33
	(b) (4)	

US3032201

Folder: Unscheduled 16 Apr 2021

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Test performed](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:40
	(b) (4)	
User entered 'Urine (URINE)'	Samantha Wieseler (b) (4)	16 Apr 2021 22:00:33
	(b) (4)	

US3032201

Folder: Unscheduled 16 Apr 2021

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Result](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:40
	(b) (4)	
User entered 'Negative (NEGATIVE)'	Samantha Wieseler (b) (4)	16 Apr 2021 22:00:33
	(b) (4)	

US3032201

Folder: Unscheduled 16 Apr 2021

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:40
	(b) (4)	
User entered 'No (N)'	Samantha Wieseler (b) (4)	16 Apr 2021 22:00:33
	(b) (4)	

US3032201

Folder: Unscheduled 16 Apr 2021

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Collection date](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:40
	(b) (4)	
User entered '16 Apr 2021'	Samantha Wieseler (b) (4)	16 Apr 2021 22:00:33
	(b) (4)	

US3032201

Folder: Unscheduled 16 Apr 2021

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Collection time](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:40
	(b) (4)	
User entered '10:27'	Samantha Wieseler (b) (4)	16 Apr 2021 22:00:33
	(b) (4)	

US3032201

Folder: Unscheduled 16 Apr 2021

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '16 Apr 2021 10:27'	System	16 Apr 2021 22:00:33

US3032201

Folder: Unscheduled 16 Apr 2021

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:40
	(b) (4)	
User entered 'No (N)'	Samantha Wieseler (b) (4)	16 Apr 2021 22:01:02
	(b) (4)	

US3032201

Folder: Unscheduled 16 Apr 2021

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:40
	(b) (4)	
User entered empty.	Samantha Wieseler (b) (4)	16 Apr 2021 22:01:02
	(b) (4)	

US3032201

Folder: Unscheduled 16 Apr 2021

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:11

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:40
	(b) (4)	
User entered empty.	Samantha Wieseler (b) (4)	16 Apr 2021 22:01:02
	(b) (4)	

US3032201

Folder: Unscheduled 16 Apr 2021

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 22:01:02

US3032201

Folder: Unscheduled 23 Apr 2021

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 21:52:11

[Visit Date](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	26 Apr 2021 06:22:04
User signature succeeded.	Keith Vrbicky (b) (4)	23 Apr 2021 19:37:17
Query 'Data is required. Please complete.' answered with 'data not required' (Site from System).	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	Samantha Wieseler (b) (4)	23 Apr 2021 14:06:08
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered '23 Apr 2021'	System	23 Apr 2021 14:06:00
	Samantha Wieseler (b) (4)	23 Apr 2021 14:06:00
	(b) (4)	
	Samantha Wieseler (b) (4)	23 Apr 2021 14:05:37
	(b) (4)	

US3032201

Folder: Unscheduled 23 Apr 2021

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 21:52:11

[Physical Exam](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	23 Apr 2021 19:37:17
User closed query 'Procedure(s) performed is missing. Please check at least one procedure from the options provided.' (Site from System).	(b) (4) System	23 Apr 2021 14:06:00
User opened query 'Procedure(s) performed is missing. Please check at least one procedure from the options provided.' (Site from System).	System	23 Apr 2021 14:05:37
User entered '0'	Samantha Wieseler (b) (4) (b) (4)	23 Apr 2021 14:05:37

US3032201

Folder: Unscheduled 23 Apr 2021

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 21:52:11

[Vital Signs](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	23 Apr 2021 19:37:17
	(b) (4)	
User entered '0'	Samantha Wieseler (b) (4)	23 Apr 2021 14:05:37
	(b) (4)	

US3032201

Folder: Unscheduled 23 Apr 2021

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 21:52:11

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	23 Apr 2021 19:37:17
	(b) (4)	
User entered '0'	Samantha Wieseler (b) (4)	23 Apr 2021 14:05:37
	(b) (4)	

US3032201

Folder: Unscheduled 23 Apr 2021

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 21:52:11

[Pregnancy Test](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	23 Apr 2021 19:37:17
	(b) (4)	
User entered '0'	Samantha Wieseler (b) (4)	23 Apr 2021 14:05:37
	(b) (4)	

US3032201

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 21:52:11

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:54:32
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
Signature has been broken.	Kelsey Kelley (b) (4)	19 Feb 2021 15:17:39
User entered 'Yes (Y)' reason for change: New Information	Kelsey Kelley (b) (4)	19 Feb 2021 15:17:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'No (N)'	Linden DeBoer (b) (4)	15 Sep 2020 23:37:39

US3032201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:11

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:47:15
User entered 'USA-US032-2021-mRNA-1273-P301000009'	System	19 Feb 2021 17:47:10
User entered 'New'	(b) (4), (b) (6)	19 Feb 2021 17:47:10

US3032201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:11

[Adverse event](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide an update regarding the outcome of the pregnancy. Please provide details regarding the delivery and infant details by completing the relevant sections of the Pregnancy Report Form' canceled (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 16:17:19
User opened query 'PV Query: Please provide an update regarding the outcome of the pregnancy. Please provide details regarding the delivery and infant details by completing the relevant sections of the Pregnancy Report Form' (Site from Safety).		01 Mar 2021 16:14:08
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User coded data point as SOC: Pregnancy, puerperium and perinatal conditions, HLGT: Pregnancy, labour, delivery and postpartum conditions, HLT: Normal pregnancy, labour and delivery, PT: Pregnancy, LLT: Pregnancy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	19 Feb 2021 15:20:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Feb 2021 15:20:51
Data point term sent to Coder	System	19 Feb 2021 15:19:54
User entered 'pregnancy'	Kelsey Kelley (b) (4)	19 Feb 2021 15:19:37

US3032201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Feb 2021 15:19:37

US3032201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Feb 2021 15:19:37

US3032201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Feb 2021 15:19:37

US3032201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
	(b) (4)	
User entered '01 Feb 2021'	Kelsey Kelley (b) (4)	19 Feb 2021 15:19:37
	(b) (4)	

US3032201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:11

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Feb 2021 15:19:37

US3032201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 15:19:37

US3032201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
	(b) (4)	
Signature has been broken.	Chelsie Nutsch (b) (4)	23 Mar 2021 21:54:18
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Chelsie Nutsch (b) (4)	23 Mar 2021 21:54:18
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	19 Feb 2021 15:19:37
	(b) (4)	

US3032201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
	(b) (4)	
Signature has been broken.	Chelsie Nutsch (b) (4)	23 Mar 2021 21:54:18
	(b) (4)	
User entered '26 Feb 2021' reason for change: Data Entry Error	Chelsie Nutsch (b) (4)	23 Mar 2021 21:54:18
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	19 Feb 2021 15:19:37
	(b) (4)	

US3032201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:11

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	19 Feb 2021 15:19:37
	(b) (4)	

US3032201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 15:19:37

US3032201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:11

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Kelsey Kelley (b) (4)	19 Feb 2021 15:19:37
	(b) (4)	

US3032201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Feb 2021 15:19:37

US3032201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	19 Feb 2021 15:19:37
	(b) (4)	

US3032201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	19 Feb 2021 15:19:37
	(b) (4)	

US3032201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Feb 2021 15:19:37

US3032201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Feb 2021 15:19:37

US3032201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:11

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Feb 2021 15:19:37

US3032201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	19 Feb 2021 15:19:37
	(b) (4)	

US3032201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Feb 2021 15:19:37

US3032201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Feb 2021 15:19:37

US3032201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Feb 2021 15:19:37

US3032201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Feb 2021 15:19:37

US3032201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Kelsey Kelley (b) (4)	19 Feb 2021 15:19:37
	(b) (4)	

US3032201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Kelsey Kelley (b) (4)	19 Feb 2021 15:19:37
	(b) (4)	

US3032201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:11

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 00:46:24
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	24 Mar 2021 00:45:59
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'updated' (Site from System).	Samantha Wieseler (b) (4)	22 Mar 2021 18:30:38
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify. ' answered with 'done' (Site from DM).	Samantha Wieseler (b) (4)	22 Mar 2021 18:30:31
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	22 Mar 2021 18:30:09
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	28 Feb 2021 02:03:58
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Kelsey Kelley (b) (4)	19 Feb 2021 15:19:37

US3032201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:11

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	19 Feb 2021 15:19:37
	(b) (4)	

US3032201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
	(b) (4)	
User entered 'I'	Kelsey Kelley (b) (4)	19 Feb 2021 15:19:37
	(b) (4)	

US3032201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	19 Feb 2021 15:19:37
	(b) (4)	

US3032201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:11

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
Signature has been broken.	(b) (4)	
	Chelsie Nutsch (b) (4)	23 Mar 2021 21:54:18
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Chelsie Nutsch (b) (4)	23 Mar 2021 21:54:18
Data Entry Error	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Kelsey Kelley (b) (4)	19 Feb 2021 15:19:37
	(b) (4)	

US3032201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:11

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	19 Feb 2021 15:19:37
	(b) (4)	

US3032201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:11

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
	(b) (4)	
Signature has been broken.	Chelsie Nutsch (b) (4)	23 Mar 2021 21:54:18
	(b) (4)	
User entered 'subject had a voluntary termination of pregnancy.' reason for change: Data Entry Error	Chelsie Nutsch (b) (4)	23 Mar 2021 21:54:18
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	19 Feb 2021 15:19:37
	(b) (4)	

US3032201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Feb 2021 15:19:37

US3032201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Feb 2021 15:19:37

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 21:52:11

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:54:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 16:37:26
User closed query 'Per CDM: Please be aware that this question is answered "No"; However, ConMeds have been entered for the subject. Please update and reconcile. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 09:48:35
Query 'Per CDM: Please be aware that this question is answered "No"; However, ConMeds have been entered for the subject. Please update and reconcile. ' answered with 'data corrected' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	27 Oct 2020 13:58:37
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	27 Oct 2020 13:58:27
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	27 Oct 2020 13:58:27
User opened query 'Per CDM: Please be aware that this question is answered "No"; However, ConMeds have been entered for the subject. Please update and reconcile. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 14:53:38
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:33:30
User entered 'No (N)' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	17 Sep 2020 16:52:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	17 Sep 2020 16:50:56
User entered 'No (N)' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	13 Aug 2020 13:54:54
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	13 Aug 2020 13:54:22

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:41
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:51:16
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Oct 2020 14:20:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Oct 2020 14:20:26
Data point term sent to Coder	System	15 Oct 2020 14:19:58
User entered 'SEASONAL INFLUENZA VACCINE'	Kelsey Kelley (b) (4)	15 Oct 2020 14:18:59

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:41
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:51:16
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	15 Oct 2020 14:18:59

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:41
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:51:16
User entered 'SEASONAL INFLUENZA PROPHYLAXIS'	Kelsey Kelley (b) (4)	15 Oct 2020 14:18:59

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:41
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:51:16
User entered '0.5'	Kelsey Kelley (b) (4)	15 Oct 2020 14:18:59

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:41
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:51:16
User entered 'mL (mL)'	(b) (4) Kelsey Kelley (b) (4)	15 Oct 2020 14:18:59

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:41
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:51:16
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	15 Oct 2020 14:18:59
	(b) (4)	

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:41
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:51:16
User entered 'once (ONCE)'	(b) (4) Kelsey Kelley (b) (4)	15 Oct 2020 14:18:59
	(b) (4)	

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:41
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:51:16
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	15 Oct 2020 14:18:59
	(b) (4)	

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:41
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:51:16
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Kelsey Kelley (b) (4)	15 Oct 2020 14:18:59
	(b) (4)	

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:41
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:51:16
User entered empty.	Kelsey Kelley (b) (4)	15 Oct 2020 14:18:59

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:11

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:41
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:51:16
User entered '13 Oct 2020'	Kelsey Kelley (b) (4)	15 Oct 2020 14:18:59

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:41
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:51:16
User entered '0'	Kelsey Kelley (b) (4)	15 Oct 2020 14:18:59

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:41
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:51:16
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	15 Oct 2020 14:18:59

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:41
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:51:16
User entered '13 Oct 2020'	Kelsey Kelley (b) (4)	15 Oct 2020 14:18:59

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:41
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:51:16
User entered 'No (N)'	Kelsey Kelley (b) (4)	15 Oct 2020 14:18:59

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:41
User entered empty.	System	15 Oct 2020 14:18:59

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:41
User entered empty.	System	15 Oct 2020 14:18:59

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:41
User entered empty.	System	15 Oct 2020 14:18:59

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:52:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:57:17
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: EMERGENCY CONTRACEPTIVES, PRODUCT: LEVONORGESTREL - version WHODrug-Global-B3\\202003.	(b) (4) (b) (4) Coder Import (b) (4)	20 Feb 2021 14:08:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 14:08:45
Data point term sent to Coder	System	19 Feb 2021 15:25:04
User entered 'Levonorgestrel'	Kelsey Kelley (b) (4) (b) (4)	19 Feb 2021 15:24:22

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:52:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:57:17
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 15:24:22

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:52:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:57:17
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'Pregnancy'	Kelsey Kelley (b) (4)	19 Feb 2021 15:24:22

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:52:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:57:17
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered '1.5'	Kelsey Kelley (b) (4)	19 Feb 2021 15:24:22

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:52:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:57:17
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 15:24:22

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:52:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:57:17
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 15:24:22
	(b) (4)	

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:52:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:57:17
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'once (ONCE)'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 15:24:22

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:52:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:57:17
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 15:24:22

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:52:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:57:17
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4)	19 Feb 2021 15:24:22

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:52:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:57:17
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered empty.	Kelsey Kelley (b) (4)	19 Feb 2021 15:24:22

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:52:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:57:17
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered '01 Feb 2021'	Kelsey Kelley (b) (4)	19 Feb 2021 15:24:22

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:52:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:57:17
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered '0'	Kelsey Kelley (b) (4)	19 Feb 2021 15:24:22

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:52:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:57:17
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 15:24:22

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:52:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:57:17
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered '01 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 15:24:22
	(b) (4)	

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:52:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:57:17
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'No (N)'	Kelsey Kelley (b) (4)	19 Feb 2021 15:24:22

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:52:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:57:17
User entered empty.	System	19 Feb 2021 15:24:22

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:52:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:57:17
User entered empty.	System	19 Feb 2021 15:24:22

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:52:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:57:17
User entered empty.	System	19 Feb 2021 15:24:22

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:52:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:57:49
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: EMERGENCY CONTRACEPTIVES, PRODUCT: LEVONORGESTREL - version WHODrug-Global-B3\\202003.	(b) (4) (b) (4) Coder Import (b) (4)	20 Feb 2021 14:08:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Feb 2021 14:08:46
Data point term sent to Coder	System	19 Feb 2021 15:25:05
User entered 'levonorgestrel'	Kelsey Kelley (b) (4) (b) (4)	19 Feb 2021 15:25:01

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:52:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:57:49
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'No (N)'	Kelsey Kelley (b) (4)	19 Feb 2021 15:25:01

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:52:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:57:49
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'Pregnancy'	Kelsey Kelley (b) (4)	19 Feb 2021 15:25:01

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:52:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:57:49
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered '1.5'	Kelsey Kelley (b) (4)	19 Feb 2021 15:25:01

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:52:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:57:49
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	19 Feb 2021 15:25:01

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:52:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:57:49
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 15:25:01
	(b) (4)	

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:52:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:57:49
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'once (ONCE)'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 15:25:01

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:52:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:57:49
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 15:25:01
	(b) (4)	

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:52:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:57:49
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4)	19 Feb 2021 15:25:01

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:52:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:57:49
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered empty.	Kelsey Kelley (b) (4)	19 Feb 2021 15:25:01

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:52:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:57:49
User closed query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	22 Mar 2021 18:29:39
User opened query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	22 Mar 2021 18:29:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered '03 Feb 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Feb 2021 15:25:01

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:52:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:57:49
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered '0'	Kelsey Kelley (b) (4)	19 Feb 2021 15:25:01

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:52:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:57:49
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'No (N)'	Kelsey Kelley (b) (4)	19 Feb 2021 15:25:01

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:52:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:57:49
User closed query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	22 Mar 2021 18:29:39
User opened query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	22 Mar 2021 18:29:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered '03 Feb 2021'	Kelsey Kelley (b) (4)	19 Feb 2021 15:25:01

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:52:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:57:49
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'No (N)'	Kelsey Kelley (b) (4)	19 Feb 2021 15:25:01

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:52:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:57:49
User entered empty.	System	19 Feb 2021 15:25:01

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:52:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:57:49
User entered empty.	System	19 Feb 2021 15:25:01

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:52:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:57:49
User entered empty.	System	19 Feb 2021 15:25:01

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:52:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:28
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS, PRODUCT: MEDROXYPROGESTERONE ACETATE, PRODUCTSYNONYM: DEPO-PROVERA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 21:02:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 21:02:02
Data point term sent to Coder	System	08 Apr 2021 19:43:57
User entered 'Depo-Provera (medroxyprogesterone)'	Chelsie Nutsch (b) (4)	08 Apr 2021 19:43:34

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:52:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:28
	(b) (4)	
User entered 'Yes (Y)'	Chelsie Nutsch (b) (4)	08 Apr 2021 19:43:34
	(b) (4)	

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:52:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:28
	(b) (4)	
User entered 'contraception'	Chelsie Nutsch (b) (4)	08 Apr 2021 19:43:34
	(b) (4)	

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:52:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:28
	(b) (4)	
User entered '150'	Chelsie Nutsch (b) (4)	08 Apr 2021 19:43:34
	(b) (4)	

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:52:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:28
	(b) (4)	
User entered 'mg (mg)'	Chelsie Nutsch (b) (4)	08 Apr 2021 19:43:34
	(b) (4)	

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:52:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:28
	(b) (4)	
User entered empty.	Chelsie Nutsch (b) (4)	08 Apr 2021 19:43:34
	(b) (4)	

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:52:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:28
	(b) (4)	
User entered 'other (OTHER)'	Chelsie Nutsch (b) (4)	08 Apr 2021 19:43:34
	(b) (4)	

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:52:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:28
	(b) (4)	
User entered 'every three months'	Chelsie Nutsch (b) (4)	08 Apr 2021 19:43:34
	(b) (4)	

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:52:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:28
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	08 Apr 2021 19:43:34

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:52:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:28
	(b) (4)	
User entered empty.	Chelsie Nutsch (b) (4)	08 Apr 2021 19:43:34
	(b) (4)	

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:52:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:28
	(b) (4)	
User entered '8 Apr 2021'	Chelsie Nutsch (b) (4)	08 Apr 2021 19:43:34
	(b) (4)	

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:52:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:28
	(b) (4)	
User entered '0'	Chelsie Nutsch (b) (4)	08 Apr 2021 19:43:34
	(b) (4)	

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:52:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:28
	(b) (4)	
User entered 'Yes (Y)'	Chelsie Nutsch (b) (4)	08 Apr 2021 19:43:34
	(b) (4)	

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:52:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:28
	(b) (4)	
User entered empty.	Chelsie Nutsch (b) (4)	08 Apr 2021 19:43:34
	(b) (4)	

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:52:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:28
	(b) (4)	
User entered 'No (N)'	Chelsie Nutsch (b) (4)	08 Apr 2021 19:43:34
	(b) (4)	

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:52:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 19:43:34

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:52:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 19:43:34

US3032201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:52:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 19:43:34

US3032201

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 21:52:11

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:33:30
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	13 Aug 2020 13:55:10

US3032201

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:52:11

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:59:17
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered with 'not required' (Site from System).	(b) (4), (b) (6)	24 Mar 2021 01:01:08
User opened query 'Data is required. Please complete.' (Site from System).	Samantha Wieseler (b) (4)	22 Mar 2021 18:29:53
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered '1 Feb 2021'	System	22 Mar 2021 18:29:39
	Samantha Wieseler (b) (4)	22 Mar 2021 18:29:39
	(b) (4)	
	Samantha Wieseler (b) (4)	22 Mar 2021 18:29:09
	(b) (4)	

US3032201

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:52:11

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:59:17
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered with 'not required' (Site from System).	(b) (4), (b) (6)	24 Mar 2021 01:01:10
User opened query 'Data is required. Please complete.' (Site from System).	Samantha Wieseler (b) (4)	22 Mar 2021 18:29:59
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered 'Pregnancy (PREGNANCY)'	System	22 Mar 2021 18:29:39
	Samantha Wieseler (b) (4)	22 Mar 2021 18:29:39
	(b) (4)	
	Samantha Wieseler (b) (4)	22 Mar 2021 18:29:09
	(b) (4)	

US3032201

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:52:11

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)	29 Apr 2021 04:59:17
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
User entered empty.	Samantha Wieseler (b) (4)	22 Mar 2021 18:29:09

US3032201

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:52:11

[If reason for discontinuation is Death, main cause of death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:59:17
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	22 Mar 2021 18:29:09

US3032201

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:52:11

[If main cause of death is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:59:17
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	22 Mar 2021 18:29:09
	(b) (4)	

US3032201

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:52:11

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:59:17
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	22 Mar 2021 18:29:09
	(b) (4)	

US3032201

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:52:11

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:59:17
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:15
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	22 Mar 2021 18:29:09
	(b) (4)	

US3032201

Folder: SAE USA-US032-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:47:23
User entered 'USA-US032-2021-MRNA-1273-P301000009'	System	19 Feb 2021 17:47:10

US3032201

Folder: SAE USA-US032-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:47:23
User entered 'No (N)'	System	19 Feb 2021 17:47:10

US3032201

Folder: SAE USA-US032-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:47:23
User entered 'No (N)'	System	19 Feb 2021 17:47:10

US3032201

Folder: SAE USA-US032-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:47:23
User entered 'No (N)'	System	19 Feb 2021 17:47:10

US3032201

Folder: SAE USA-US032-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:47:23
User entered 'No (N)'	System	19 Feb 2021 17:47:10

US3032201

Folder: SAE USA-US032-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:47:23
User entered 'No (N)'	System	19 Feb 2021 17:47:10

US3032201

Folder: SAE USA-US032-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:47:23
User entered 'No (N)'	System	19 Feb 2021 17:47:10

US3032201

Folder: SAE USA-US032-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:47:23
User entered 'No (N)'	System	19 Feb 2021 17:47:10

US3032201

Folder: SAE USA-US032-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:47:23
User entered 'Keith'	System	19 Feb 2021 17:47:10

US3032201

Folder: SAE USA-US032-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:47:23
User entered 'Vrbicky'	System	19 Feb 2021 17:47:10

US3032201

Folder: SAE USA-US032-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'US'	(b) (4) System	19 Feb 2021 17:47:36

US3032201

Folder: SAE USA-US032-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'I'	(b) (4) System	19 Feb 2021 17:47:36

US3032201

Folder: SAE USA-US032-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:47:23
User entered 'USA-US032-2021-MRNA-1273-P301000009'	System	19 Feb 2021 17:47:10

US3032201

Folder: SAE USA-US032-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:47:23
User entered 'No (N)'	System	19 Feb 2021 17:47:10

US3032201

Folder: SAE USA-US032-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:47:23
User entered 'No (N)'	System	19 Feb 2021 17:47:10

US3032201

Folder: SAE USA-US032-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:47:23
User entered 'No (N)'	System	19 Feb 2021 17:47:10

US3032201

Folder: SAE USA-US032-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:47:23
User entered 'No (N)'	System	19 Feb 2021 17:47:10

US3032201

Folder: SAE USA-US032-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:47:23
User entered 'No (N)'	System	19 Feb 2021 17:47:10

US3032201

Folder: SAE USA-US032-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:47:23
User entered 'No (N)'	System	19 Feb 2021 17:47:10

US3032201

Folder: SAE USA-US032-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:47:23
User entered 'No (N)'	System	19 Feb 2021 17:47:10

US3032201

Folder: SAE USA-US032-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:47:23
User entered 'Keith'	System	19 Feb 2021 17:47:10

US3032201

Folder: SAE USA-US032-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:47:23
User entered 'Vrbicky'	System	19 Feb 2021 17:47:10

US3032201

Folder: SAE USA-US032-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'US'	(b) (4) System	19 Feb 2021 17:47:36

US3032201

Folder: SAE USA-US032-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'I'	(b) (4) System	19 Feb 2021 17:47:36

US3032201

Folder: SAE USA-US032-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 21:52:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered '19/Feb/2021 12:47'	(b) (4) System	19 Feb 2021 17:47:36

US3032201

Folder: SAE USA-US032-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 21:52:11

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:31
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:47:36