

US3032211 (Prod: Meridian Clinical Research (Norfolk-Nebraska))

Generated By: KC Joubran

Generated On: 11 Aug 2021 21:53:47

All time stamps listed in this document are displayed in GMT

US3032211

Form: Participant Creation

Data signed: (b) (4) 28 Sep 2020 17:37:16

Generated On: 11 Aug 2021 21:53:47

Participant ID

US3032211

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

US3032211

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 17:37:17

Generated On: 11 Aug 2021 21:53:47

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

Visit date (dd MMM yyyy)	18 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3032211

Folder: Screening

Form: Demographics

Data signed: (b) (4) 28 Sep 2020 17:37:17

Generated On: 11 Aug 2021 21:53:47

Date of Birth (MMM yyyy)	(b) (6)	1977
Age		43
Age Units		YEARS
Age (Derived)		43
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

US3032211

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 28 Sep 2020 17:37:17

Generated On: 11 Aug 2021 21:53:47

Date of Informed Consent (<i>dd MMM yyyy</i>)	18 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

US3032211

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 28 Sep 2020 17:37:17

Generated On: 11 Aug 2021 21:53:47

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3032211

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 28 Sep 2020 17:37:17

Generated On: 11 Aug 2021 21:53:47

Were any significant conditions reported?

Yes ☒
No ☐

US3032211

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 28 Sep 2020 17:37:17

Generated On: 11 Aug 2021 21:53:47

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3032211

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 28 Sep 2020 17:37:17

Generated On: 11 Aug 2021 21:53:47

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

US3032211

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 28 Sep 2020 17:37:17

Generated On: 11 Aug 2021 21:53:47

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

US3032211

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 08 Oct 2020 15:37:16

Generated On: 11 Aug 2021 21:53:47

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 AUG 2020
Time of assessment (00:00-23:59)	11:25 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 11:25
Height (xxx.x)	166.3 cm
Weight (xxx.x)	102.0 kg
BMI (xxx.x)	36.88210 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3032211

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 17:37:17

Generated On: 11 Aug 2021 21:53:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 AUG 2020

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

US3032211

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 28 Sep 2020 17:37:17

Generated On: 11 Aug 2021 21:53:47

Date of assessment (dd MMM yyyy) 18 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

US3032211

Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 28 Sep 2020 17:37:17

Generated On: 11 Aug 2021 21:53:47

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 18 AUG 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

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

US3032211

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Sep 2020 17:37:17

Generated On: 11 Aug 2021 21:53:47

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

US3032211

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Sep 2020 17:37:17

Generated On: 11 Aug 2021 21:53:47

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	

US3032211

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 17:37:17

Generated On: 11 Aug 2021 21:53:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3032211

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 02 Nov 2020 22:11:27

Generated On: 11 Aug 2021 21:53:47

What was the date of randomization? (dd MMM yyyy) 18 AUG 2020

What was the participant's randomization number? 105468

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 ☒

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Oct 2020 13:56:35

Generated On: 11 Aug 2021 21:53:47

Height	ND - Not Done
Weight	ND - Not Done

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Oct 2020 13:56:35

Generated On: 11 Aug 2021 21:53:47

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)	18 AUG 2020
Time of assessment (00:00-23:59)	11:25 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 11:25
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)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Oct 2020 13:56:35

Generated On: 11 Aug 2021 21:53:47

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)	18 AUG 2020
Time of assessment (00:00-23:59)	13:00 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 13:00
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3032211

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 17:37:17

Generated On: 11 Aug 2021 21:53:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 AUG 2020

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

US3032211

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 28 Oct 2020 16:37:46

Generated On: 11 Aug 2021 21:53:47

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) _____

US3032211

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 28 Sep 2020 17:37:17

Generated On: 11 Aug 2021 21:53:47

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) 18 AUG 2020

What was the treatment time? (00:00-23:59) 12:25 (24 HR)

Treatment Date and Time (derived) 18 AUG 2020 12:25

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

US3032211

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Dec 2020 19:48:17

Generated On: 11 Aug 2021 21:53:47

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 AUG 2020

Collection time (00:00-23:59)

11:45 (24 HR)

Collection date and time (derived)

18 AUG 2020 11:45

US3032211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Sep 2020 17:37:17

Generated On: 11 Aug 2021 21:53:47

Collection date (dd MMM yyyy)			18 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:36	18 AUG 2020 11:36
Nasopharyngeal Swab 2	No		

US3032211

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:37:17

Generated On: 11 Aug 2021 21:53:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:53:47

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

98.2 °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

18 AUG 2020 13:00

PC Open Date & Time

18 AUG 2020 12:45

PC Close Date & Time

18 AUG 2020 15:15

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.3 °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	18 AUG 2020 16:58
PC Open Date & Time	18 AUG 2020 16:10
PC Close Date & Time	19 AUG 2020 11:59

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:53:47

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

97.8 °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

19 AUG 2020 12:05

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

20 AUG 2020 17:26

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

21 AUG 2020 12:29

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:53:47

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

97.2 °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

22 AUG 2020 16:46

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:53:47

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

97.3 °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

23 AUG 2020 15:14

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:53:47

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

97.5 °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

24 AUG 2020 13:35

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:53:47

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

18 AUG 2020 13:00

PC Open Date & Time

18 AUG 2020 12:45

PC Close Date & Time

18 AUG 2020 15:15

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:53:47

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

18 AUG 2020 16:58

PC Open Date & Time

18 AUG 2020 16:10

PC Close Date & Time

19 AUG 2020 11:59

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:53:47

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

19 AUG 2020 12:06

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:53:47

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

20 AUG 2020 17:27

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:53:47

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

21 AUG 2020 12:30

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:53:47

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

22 AUG 2020 16:46

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:53:47

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

23 AUG 2020 15:14

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:53:47

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

24 AUG 2020 13:36

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:47

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 ☐

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:47

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

No ☒

Yes ☐

PC Time stamp	18 AUG 2020 13:01
PC Open Date & Time	18 AUG 2020 12:45
PC Close Date & Time	18 AUG 2020 15:15

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:47

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 ☐

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:47

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

No ☒

Yes ☐

PC Time stamp	18 AUG 2020 16:59
PC Open Date & Time	18 AUG 2020 16:10
PC Close Date & Time	19 AUG 2020 11:59

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:47

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 ☒

PRODUCTION RELEASE (v12.003

47 of 1790

EAB) (1725)

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:47

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 12:06
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:47

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 ☒

PRODUCTION RELEASE (v12.003

49 of 1790

EAB) (1725)

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:47

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 17:27
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:47

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 ☒

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:47

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 12:30
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

53 of 1790

EAB) (1725)

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:47

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 16:47
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

55 of 1790

EAB) (1725)

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:47

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 15:15
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:47

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 ☒

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:47

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 13:36
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3032211

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 17:37:16

Generated On: 11 Aug 2021 21:53:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032211

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:37:16

Generated On: 11 Aug 2021 21:53:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032211

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 17:37:16

Generated On: 11 Aug 2021 21:53:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032211

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:37:16

Generated On: 11 Aug 2021 21:53:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032211

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 17:37:16

Generated On: 11 Aug 2021 21:53:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032211

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:37:16

Generated On: 11 Aug 2021 21:53:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032211

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 17:37:17

Generated On: 11 Aug 2021 21:53:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 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

US3032211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Dec 2020 19:48:17

Generated On: 11 Aug 2021 21:53:47

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 SEP 2020
Time of assessment (00:00-23:59)	08:18 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 08:18
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)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3032211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Dec 2020 19:48:17

Generated On: 11 Aug 2021 21:53:47

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

US3032211

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 17:37:17

Generated On: 11 Aug 2021 21:53:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 SEP 2020

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

US3032211

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 28 Sep 2020 17:37:17

Generated On: 11 Aug 2021 21:53:47

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 17 SEP 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

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

US3032211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 28 Sep 2020 17:37:17

Generated On: 11 Aug 2021 21:53:47

Was study treatment given? Yes ☐
No ☒

If No, reason not given

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

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

What was the study treatment?

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3032211

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Sep 2020 17:37:17

Generated On: 11 Aug 2021 21:53:47

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 SEP 2020

Collection time (00:00-23:59)

08:44 (24 HR)

Collection date and time (derived)

17 SEP 2020 08:44

US3032211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Sep 2020 17:37:17

Generated On: 11 Aug 2021 21:53:47

Collection date (dd MMM yyyy)			17 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:36	17 SEP 2020 08:36
Nasopharyngeal Swab 2	No		

US3032211

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:37:17

Generated On: 11 Aug 2021 21:53:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032211

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 08 Dec 2020 19:48:17

Generated On: 11 Aug 2021 21:53:47

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

US3032211

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Oct 2020 13:56:34

Generated On: 11 Aug 2021 21:53:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032211

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 08 Dec 2020 19:48:17

Generated On: 11 Aug 2021 21:53:47

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

US3032211

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Oct 2020 13:56:35

Generated On: 11 Aug 2021 21:53:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032211

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 14 Oct 2020 19:33:27

Generated On: 11 Aug 2021 21:53:47

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3032211

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 14 Oct 2020 19:33:27

Generated On: 11 Aug 2021 21:53:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032211

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 14 Oct 2020 19:33:27

Generated On: 11 Aug 2021 21:53:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 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

US3032211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 14 Oct 2020 19:33:27

Generated On: 11 Aug 2021 21:53:47

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	08:11 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 08:11
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)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3032211

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Oct 2020 19:33:27

Generated On: 11 Aug 2021 21:53:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 OCT 2020

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

US3032211

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Oct 2020 19:33:27

Generated On: 11 Aug 2021 21:53:47

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 OCT 2020
Collection time (00:00-23:59)	08:32 (24 HR)
Collection date and time (derived)	13 OCT 2020 08:32

US3032211

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 14 Oct 2020 19:33:27

Generated On: 11 Aug 2021 21:53:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 OCT 2020 12:00:46

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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 <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"/>

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

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

Date and time of submission

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

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

Date and time of submission

Patient Cloud Open Date & Time

01 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

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

Date and time of submission

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2020 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2020 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

03 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2020 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

17 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2020 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2020 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

31 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

07 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 JAN 2021 02:11:00

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

21 JAN 2021 10:25:50

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

28 JAN 2021 01:46:29

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

07 FEB 2021 16:09:34

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 FEB 2021 06:30:44

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

21 FEB 2021 07:30:50

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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	01 MAR 2021 00:00:05
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 MAR 2021 05:22:00

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

11 MAR 2021 00:12:50

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

18 MAR 2021 00:02:22

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

25 MAR 2021 01:17:25

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

01 APR 2021 02:01:11

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 APR 2021 06:21:15

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 APR 2021 10:22:15
Patient Cloud Open Date & Time	15 APR 2021 00:01
Patient Cloud Close Date & Time	19 APR 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 APR 2021 00:02:59
Patient Cloud Open Date & Time	22 APR 2021 00:01
Patient Cloud Close Date & Time	26 APR 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

29 APR 2021 02:33:54

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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="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"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

Have you experienced any new COVID-19 disease symptoms 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):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUN 2021 00:01
Patient Cloud Close Date & Time	14 JUN 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2021 00:01
Patient Cloud Close Date & Time	19 JUL 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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="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"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

Have you experienced any new COVID-19 disease symptoms 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):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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="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"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

Have you experienced any new COVID-19 disease symptoms 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):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

Have you experienced any new COVID-19 disease symptoms 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):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

Have you experienced any new COVID-19 disease symptoms 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):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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="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"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

16 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 DEC 2021 00:01
Patient Cloud Close Date & Time	27 DEC 2021 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

Have you experienced any new COVID-19 disease symptoms 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):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

Have you experienced any new COVID-19 disease symptoms 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):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 FEB 2022 00:01
Patient Cloud Close Date & Time	07 FEB 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

Have you experienced any new COVID-19 disease symptoms 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):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

Have you experienced any new COVID-19 disease symptoms 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):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

Have you experienced any new COVID-19 disease symptoms 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):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

Have you experienced any new COVID-19 disease symptoms 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):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

Have you experienced any new COVID-19 disease symptoms 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):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

Have you experienced any new COVID-19 disease symptoms 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):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

Have you experienced any new COVID-19 disease symptoms 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):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 APR 2022 00:01
Patient Cloud Close Date & Time	18 APR 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

Have you experienced any new COVID-19 disease symptoms 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):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 JUN 2022 00:01
Patient Cloud Close Date & Time	20 JUN 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

Have you experienced any new COVID-19 disease symptoms 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):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 JUL 2022 00:01
Patient Cloud Close Date & Time	18 JUL 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2022 00:01
Patient Cloud Close Date & Time	25 JUL 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

Have you experienced any new COVID-19 disease symptoms 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):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

Have you experienced any new COVID-19 disease symptoms 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):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

25 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 SEP 2022 00:01
Patient Cloud Close Date & Time	19 SEP 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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="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"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 SEP 2022 00:01
Patient Cloud Close Date & Time	26 SEP 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

Have you experienced any new COVID-19 disease symptoms 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):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

[Patient Cloud Open Date & Time](#)

13 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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"/>

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

Date and time of submission	
Patient Cloud Open Date & Time	20 OCT 2022 00:01
Patient Cloud Close Date & Time	24 OCT 2022 23:59

US3032211

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 21:53:47

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		28 FEB 2021 23:59:48

US3032211

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 15:37:38

Generated On: 11 Aug 2021 21:53:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032211

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 15:37:38

Generated On: 11 Aug 2021 21:53:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032211

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 15:37:35

Generated On: 11 Aug 2021 21:53:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032211

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 15:37:35

Generated On: 11 Aug 2021 21:53:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032211

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 15:37:36

Generated On: 11 Aug 2021 21:53:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032211

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 15:37:36

Generated On: 11 Aug 2021 21:53:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032211

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 15:37:37

Generated On: 11 Aug 2021 21:53:47

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3032211

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 15:37:37

Generated On: 11 Aug 2021 21:53:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032211

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 18 Mar 2021 21:16:19

Generated On: 11 Aug 2021 21:53:47

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

Visit date (dd MMM yyyy)	15 MAR 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	VISIT4
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US3032211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 15:39:10

Generated On: 11 Aug 2021 21:53:47

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) _____

US3032211

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Mar 2021 21:16:19

Generated On: 11 Aug 2021 21:53:47

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.

US3032211

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Mar 2021 21:16:19

Generated On: 11 Aug 2021 21:53:47

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 MAR 2021

Collection time (00:00-23:59)

09:30 (24 HR)

Collection date and time (derived)

15 MAR 2021 09:30

US3032211

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:16:19

Generated On: 11 Aug 2021 21:53:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032211

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 19 Apr 2021 15:26:50

Generated On: 11 Aug 2021 21:53:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032211

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 19 Apr 2021 15:26:50

Generated On: 11 Aug 2021 21:53:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032211

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

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

US3032211

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3032211

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 24 Nov 2020 20:28:49

Generated On: 11 Aug 2021 21:53:47

Date of Contact	10 SEP 2020
Time of Contact	10:50
Date and Time of Contact (derived)	10 SEP 2020 10:50
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input type="checkbox"/></div> <div>No<input checked="" type="checkbox"/></div>

US3032211

Folder: Covid-19 Assessment 10 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 24 Nov 2020 20:28:49

Generated On: 11 Aug 2021 21:53:47

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3032211

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

Form: Visit Date

Data signed: (b) (4) 05 Feb 2021 19:41:02

Generated On: 11 Aug 2021 21:53:47

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

Visit date (dd MMM yyyy)	13 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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US3032211

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

Form: Unblinding

Data signed: (b) (4) 10 Mar 2021 15:37:35

Generated On: 11 Aug 2021 21:53:47

Date of updated informed consent (<i>dd MMM yyyy</i>)	9 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>)	9 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

US3032211

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 18 Jan 2021 19:29:45

Generated On: 11 Aug 2021 21:53:47

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

US3032211

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Jan 2021 19:29:45

Generated On: 11 Aug 2021 21:53:47

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)	13 JAN 2021
Time of assessment (00:00-23:59)	14:51 (24 HR)
Vital Signs Date and Time (derived)	13 JAN 2021 14:51
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3032211

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Jan 2021 19:29:45

Generated On: 11 Aug 2021 21:53:47

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)	13 JAN 2021
Time of assessment (00:00-23:59)	15:57 (24 HR)
Vital Signs Date and Time (derived)	13 JAN 2021 15:57
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)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3032211

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

Form: Physical Examination

Data signed: (b) (4) 18 Jan 2021 19:29:45

Generated On: 11 Aug 2021 21:53:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 JAN 2021

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

US3032211

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

Form: Pregnancy Test

Data signed: (b) (4) 18 Jan 2021 19:29:45

Generated On: 11 Aug 2021 21:53:47

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 13 JAN 2021

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

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

US3032211

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

Form: Exposure

Data signed: (b) (4) 18 Jan 2021 19:29:45

Generated On: 11 Aug 2021 21:53:47

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) 13 JAN 2021

What was the treatment time? (00:00-23:59) 15:25 (24 HR)

Treatment Date and Time (derived) 13 JAN 2021 15:25

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

US3032211

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 17:25:41

Generated On: 11 Aug 2021 21:53:47

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 JAN 2021

Collection time (00:00-23:59)

12:43 (24 HR)

Collection date and time (derived)

13 JAN 2021 12:43

US3032211

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 18 Jan 2021 19:29:45

Generated On: 11 Aug 2021 21:53:47

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 JAN 2021
Collection time (00:00 - 23:59)	12:47
Collection Date and Time (derived)	9 JAN 2021 12:47

US3032211

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

Form: Continuing

Data signed: (b) (4) 18 Jan 2021 19:29:45

Generated On: 11 Aug 2021 21:53:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032211

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:56:06

Generated On: 11 Aug 2021 21:53:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032211

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:56:06

Generated On: 11 Aug 2021 21:53:47

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

US3032211

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:56:06

Generated On: 11 Aug 2021 21:53:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 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

US3032211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 19:56:06

Generated On: 11 Aug 2021 21:53:47

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)	9 FEB 2021
Time of assessment (00:00-23:59)	11:36 (24 HR)
Vital Signs Date and Time (derived)	9 FEB 2021 11:36
Temperature (xxx.x)	37.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3032211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 19:56:06

Generated On: 11 Aug 2021 21:53:47

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)	9 FEB 2021
Time of assessment (00:00-23:59)	12:45 (24 HR)
Vital Signs Date and Time (derived)	9 FEB 2021 12:45
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)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3032211

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:56:06

Generated On: 11 Aug 2021 21:53:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 FEB 2021

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

US3032211

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 12 Feb 2021 19:56:06

Generated On: 11 Aug 2021 21:53:47

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	9 FEB 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)	

US3032211

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 19:56:06

Generated On: 11 Aug 2021 21:53:47

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) 9 FEB 2021

What was the treatment time? (00:00-23:59) 12:10 (24 HR)

Treatment Date and Time (derived) 9 FEB 2021 12:10

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

US3032211

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:56:06

Generated On: 11 Aug 2021 21:53:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032211

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 15:37:38

Generated On: 11 Aug 2021 21:53:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032211

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 15:37:38

Generated On: 11 Aug 2021 21:53:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032211

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 18 Mar 2021 21:16:19

Generated On: 11 Aug 2021 21:53:47

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID OLD57

US3032211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

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

US3032211

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:53:47

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.

US3032211

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:47

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

Collection date (<i>dd MMM yyyy</i>)	_____
Collection time (<i>00:00-23:59</i>)	_____
Collection date and time (derived)	_____

US3032211

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 07 Jan 2021 19:17:24

Generated On: 11 Aug 2021 21:53:47

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Jan 2021 16:51:20

Generated On: 11 Aug 2021 21:53:47

AEID	USA-US032-2020-MRNA-1273-P30 1000019
Adverse event	SARSCOV-2 INFECTION
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)	18 AUG 2020
Start time (00:00-23:59)	08:00 (24 HR)
AE start date and time (derived)	18 AUG 2020 08:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	18 AUG 2020
End time (00:00-23:59)	08:01 (24 HR)
AE End Date and Time (derived)	18 AUG 2020 08:01
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)

325 of 1790

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Jan 2021 16:51:20

Generated On: 11 Aug 2021 21:53:47

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

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Sep 2020 17:37:16

Generated On: 11 Aug 2021 21:53:47

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

Yes ☒

No ☐

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

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 06 Apr 2021 15:39:10

Generated On: 11 Aug 2021 21:53:47

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication MEDICAL HISTORY:
HYPOTHYROIDISM

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

328 of 1790

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 06 Apr 2021 15:39:10

Generated On: 11 Aug 2021 21:53:47

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 06 Apr 2021 15:39:10

Generated On: 11 Aug 2021 21:53:47

Name of Medication SERTRALINE

Prophylaxis Yes ☐
No ☒

Indication MEDICAL HISTORY:
DEPRESSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

330 of 1790

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 06 Apr 2021 15:39:10

Generated On: 11 Aug 2021 21:53:47

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 06 Apr 2021 15:39:10

Generated On: 11 Aug 2021 21:53:47

Name of Medication SEASONAL FLU VACCINE

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF SEASONAL
FLU

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

332 of 1790

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 06 Apr 2021 15:39:10

Generated On: 11 Aug 2021 21:53:47

	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)	02 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		02 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3032211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Sep 2020 17:37:16

Generated On: 11 Aug 2021 21:53:47

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3032211

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 08 Dec 2020 19:48:16

Generated On: 11 Aug 2021 21:53:47

Date of dosing discontinuation (dd MMM yyyy) 17 SEP 2020

Primary reason for dosing discontinuation

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

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

US3032211

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:53:47

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 ☐

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 08 Dec 2020 19:48:16

Generated On: 11 Aug 2021 21:53:47

SAEID	USA-US032-2020-MRNA-1273-P301000001
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)	2

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 08 Dec 2020 19:48:16

Generated On: 11 Aug 2021 21:53:47

SAEID	USA-US032-2020-MRNA-1273-P301000001
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)	2
Date of submission (Pre-filled from custom function)	07/SEP/2020 14:39
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

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 08 Dec 2020 19:48:16

Generated On: 11 Aug 2021 21:53:47

SAEID	USA-US032-2020-MRNA-1273-P301000001
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)	2
Date of submission (Pre-filled from custom function)	05/DEC/2020 15:10
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.	False

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Data signed: (b) (4) 30 Jan 2021 16:51:20

Generated On: 11 Aug 2021 21:53:47

SAEID	USA-US032-2020-MRNA-1273-P301000019
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)	4

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form (1)

Data signed: (b) (4) 30 Jan 2021 16:51:20

Generated On: 11 Aug 2021 21:53:47

SAEID	USA-US032-2020-MRNA-1273-P301000019
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)	4
Date of submission (Pre-filled from custom function)	05/DEC/2020 15:29
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form (2)

Data signed: (b) (4) 30 Jan 2021 16:51:20

Generated On: 11 Aug 2021 21:53:47

SAEID	USA-US032-2020-MRNA-1273-P301000019
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)	4
Date of submission (Pre-filled from custom function)	31/DEC/2020 00:52
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form (3)

Data signed: (b) (4) 30 Jan 2021 16:51:20

Generated On: 11 Aug 2021 21:53:47

SAEID	USA-US032-2020-MRNA-1273-P301000019
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)	4
Date of submission (Pre-filled from custom function)	11/JAN/2021 15:14
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form (4)

Data signed: (b) (4) 30 Jan 2021 16:51:20

Generated On: 11 Aug 2021 21:53:47

SAEID	USA-US032-2020-MRNA-1273-P301000019
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)	4
Date of submission (Pre-filled from custom function)	20/JAN/2021 20:22
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

US3032211 (Prod: Meridian Clinical Research (Norfolk-Nebraska))

US3032211

Form: Participant Creation

Generated On: 11 Aug 2021 21:53:47

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:58:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'US3032211'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 16:29:34

US3032211

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:53:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:26:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Aug 2020 17:38:42

US3032211

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:26:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '18 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 16:29:35

US3032211

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:26:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Clinic (Clinic)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Aug 2020 17:38:42

US3032211

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:53:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered 'SCRN'	System	18 Aug 2020 17:38:42

US3032211

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:28:22
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered (b) (6) 1977'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 16:29:36

US3032211

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:53:47

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:28:22
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '43'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Aug 2020 17:38:54

US3032211

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:53:47

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered 'YEARS'	System	18 Aug 2020 17:38:54

US3032211

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:53:47

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered '43'	System	18 Aug 2020 17:39:22

US3032211

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:53:47

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:28:22
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Female (F)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Aug 2020 17:38:54

US3032211

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:53:47

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:28:22
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Aug 2020 17:38:54

US3032211

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:53:47

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:28:22
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'l'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Aug 2020 17:38:54

US3032211

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:53:47

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:28:22
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Aug 2020 17:38:54

US3032211

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:53:47

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:28:22
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Aug 2020 17:38:54

US3032211

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:53:47

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:28:22
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Aug 2020 17:38:54

US3032211

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:53:47

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:28:22
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Aug 2020 17:38:54

US3032211

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:53:47

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:28:22
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Aug 2020 17:38:54

US3032211

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:53:47

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:28:22
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Aug 2020 17:38:54

US3032211

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:53:47

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:28:22
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Aug 2020 17:38:54

US3032211

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:53:47

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:28:22
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Aug 2020 17:38:54

US3032211

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:53:47

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:28:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '18 Aug 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Aug 2020 17:39:22

US3032211

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered 'Aug 2020'	System	18 Aug 2020 17:39:22

US3032211

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered '2020'	System	18 Aug 2020 17:39:22

US3032211

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:53:47

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:28:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Amendment 2 (2)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Aug 2020 17:39:22

US3032211

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:28:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Aug 2020 17:39:22

US3032211

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:28:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Aug 2020 17:39:22

US3032211

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:53:47

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:28:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4)	
	Linden DeBoer (b) (4)	18 Aug 2020 17:39:22
	(b) (4)	

US3032211

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:53:47

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:28:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Aug 2020 17:39:22

US3032211

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:53:47

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:28:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 16:29:35

US3032211

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:53:47

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered '1'	System	18 Aug 2020 17:40:42

US3032211

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:28:10
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Yes (Y)'	(b) (4)	
	Linden DeBoer (b) (4)	18 Aug 2020 17:40:42
	(b) (4)	

US3032211

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 21:53:47

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	18 Aug 2020 18:30:57

US3032211

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:53:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:28:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	18 Aug 2020 22:20:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 22:20:44
Data point term sent to Coder	System	18 Aug 2020 18:31:21
User entered 'seasonal allergies'	Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:31:21

US3032211

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:28:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'un UNK 1980'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:31:21

US3032211

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:53:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:28:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:31:21

US3032211

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:53:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:28:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:31:21

US3032211

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:28:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:31:21

US3032211

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:53:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:28:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:31:21

US3032211

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered 'Jan 1980'	System	18 Aug 2020 18:31:21

US3032211

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered '1980'	System	18 Aug 2020 18:31:21

US3032211

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered empty.	System	18 Aug 2020 18:31:21

US3032211

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered empty.	System	18 Aug 2020 18:31:21

US3032211

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:53:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:28:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	(b) (4) (b) (4) Coder Import	18 Aug 2020 22:24:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 22:24:48
Data point term sent to Coder	System	18 Aug 2020 18:32:22
User entered 'hypothyroidism'	Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:31:32

US3032211

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:28:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'un UNK 2018'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:31:32

US3032211

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:53:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:28:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:31:32

US3032211

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:53:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:28:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:31:32

US3032211

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:28:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:31:32

US3032211

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:53:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:28:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:31:32

US3032211

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered 'Jan 2018'	System	18 Aug 2020 18:31:32

US3032211

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered '2018'	System	18 Aug 2020 18:31:32

US3032211

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered empty.	System	18 Aug 2020 18:31:32

US3032211

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered empty.	System	18 Aug 2020 18:31:32

US3032211

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:53:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:28:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	(b) (4) (b) (4) Coder Import (b) (4)	18 Aug 2020 22:24:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 22:24:48
Data point term sent to Coder	System	18 Aug 2020 18:32:22
User entered 'depression'	Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:31:42

US3032211

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:28:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'un UNK 2018'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:31:42

US3032211

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:53:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:28:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:31:42

US3032211

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:53:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:28:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:31:42

US3032211

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:28:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:31:42

US3032211

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:53:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:28:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:31:42

US3032211

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered 'Jan 2018'	System	18 Aug 2020 18:31:42

US3032211

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered '2018'	System	18 Aug 2020 18:31:42

US3032211

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered empty.	System	18 Aug 2020 18:31:42

US3032211

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered empty.	System	18 Aug 2020 18:31:42

US3032211

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:29:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:27:57

US3032211

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:29:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '18 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:27:57

US3032211

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:29:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '11:25'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:27:57

US3032211

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered '18 Aug 2020 11:25'	System	18 Aug 2020 18:27:57

US3032211

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:29:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '166.3' cm	(b) (4) Kelsey Kelley (b) (4)	18 Aug 2020 18:27:57
DataPoint set to visible.	(b) (4) System	18 Aug 2020 17:40:42

US3032211

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:29:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '102.0' kg	(b) (4) Kelsey Kelley (b) (4)	18 Aug 2020 18:27:57
DataPoint set to visible.	(b) (4) System	18 Aug 2020 17:40:42

US3032211

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
Amendment Manager: User entered '36.88210'	System	17 Sep 2020 00:12:11
User entered '36.9'	System	18 Aug 2020 18:27:57
DataPoint set to visible.	System	18 Aug 2020 17:40:42

US3032211

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered 'kg/m2'	System	18 Aug 2020 18:27:57
DataPoint set to visible.	System	18 Aug 2020 17:40:42

US3032211

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:29:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:37:16
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 06:53:56
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 14:44:13
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 14:44:04
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 14:44:04
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 11:36:23
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:37:18
User entered '36.7' C	Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:27:57

US3032211

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:29:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:37:16
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	07 Oct 2020 14:44:04
	(b) (4)	
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4)	07 Oct 2020 14:44:04
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
	(b) (4)	
User entered 'Oral (Oral)'	Kelsey Kelley (b) (4)	18 Aug 2020 18:27:57
	(b) (4)	

US3032211

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:29:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:27:57

US3032211

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:29:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:37:16
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	07 Oct 2020 14:44:04
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	07 Oct 2020 14:44:04
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
	(b) (4)	
User entered '71'	Kelsey Kelley (b) (4)	18 Aug 2020 18:27:57
	(b) (4)	

US3032211

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered 'bpm'	System	18 Aug 2020 18:27:57

US3032211

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:29:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:37:16
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	07 Oct 2020 14:44:04
	(b) (4)	
User entered missing code ND - Not Done; reason for	Linden DeBoer (b) (4)	07 Oct 2020 14:44:04
change Data Entry Error	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
	(b) (4)	
User entered '16'	Kelsey Kelley (b) (4)	18 Aug 2020 18:27:57
	(b) (4)	

US3032211

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered 'breaths/min'	System	18 Aug 2020 18:27:57

US3032211

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:29:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:37:16
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	07 Oct 2020 14:44:04
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	07 Oct 2020 14:44:04
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
	(b) (4)	
User entered '126'	Kelsey Kelley (b) (4)	18 Aug 2020 18:27:57
	(b) (4)	

US3032211

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered 'mmHg'	System	18 Aug 2020 18:27:57

US3032211

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:29:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:37:16
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	07 Oct 2020 14:44:04
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	07 Oct 2020 14:44:04
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
	(b) (4)	
User entered '73'	Kelsey Kelley (b) (4)	18 Aug 2020 18:27:57
	(b) (4)	

US3032211

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered 'mmHg'	System	18 Aug 2020 18:27:57

US3032211

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48

US3032211

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48

US3032211

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 21:53:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:29:50
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:23:31

US3032211

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 21:53:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:29:50
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '18 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:23:31

US3032211

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:53:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:30:07
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '18 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:26:46

US3032211

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:30:07
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:26:46

US3032211

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:30:07
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:26:46

US3032211

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:30:07
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:26:46

US3032211

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:30:07
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:26:46

US3032211

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:53:47

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:30:07
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:26:46

US3032211

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:30:07
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:26:46

US3032211

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:53:47

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:30:07
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:26:46

US3032211

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:30:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:27:05

US3032211

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:30:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '18 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:27:05

US3032211

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:30:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Urine (URINE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:27:05

US3032211

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:30:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Negative (NEGATIVE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:27:05

US3032211

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:30:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:27:05

US3032211

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:30:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:27:05

US3032211

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:30:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:27:05

US3032211

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered empty.	System	18 Aug 2020 18:27:05

US3032211

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:30:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:24:34

US3032211

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:30:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:24:34

US3032211

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:30:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:24:34

US3032211

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:30:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:24:34

US3032211

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:47

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:30:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Aug 2020 18:24:45
User entered 'No (N)' reason for change: Data Entry Error	System	18 Aug 2020 18:24:45
User entered 'No (N)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	18 Aug 2020 18:24:45
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	18 Aug 2020 18:24:34
	Kelsey Kelley (b) (4)	18 Aug 2020 18:24:34
	(b) (4)	

US3032211

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:30:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:24:34

US3032211

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:30:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:24:34

US3032211

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:30:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:24:34

US3032211

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:30:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:24:34

US3032211

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:30:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:24:34

US3032211

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:30:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:24:34

US3032211

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:47

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:30:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:24:34

US3032211

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:47

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:30:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:24:34

US3032211

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:47

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'I'	(b) (4) Kelsey Kelley (b) (4)	18 Aug 2020 18:24:34
	(b) (4)	

US3032211

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:30:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:24:34

US3032211

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:30:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:24:34

US3032211

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:30:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:24:34

US3032211

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:30:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:24:34

US3032211

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:30:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:24:34

US3032211

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:47

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '0'	Kelsey Kelley (b) (4)	18 Aug 2020 18:24:34

US3032211

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:47

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
DataPoint Verified.		17 Dec 2020 18:30:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:24:34

US3032211

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:53:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:23:10

US3032211

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:53:47

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '18 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:23:10

US3032211

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:53:47

[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 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:23:10

US3032211

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:53:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User entered 'VISIT1'	System	18 Aug 2020 18:23:10

US3032211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '18 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 16:49:47

US3032211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:53:47

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 05:19:14
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:19:14
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Aug 2020 16:49:47
User entered '105468' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 16:49:47

US3032211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 16:49:47

US3032211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:53:47

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 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:23:20

US3032211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:53:47

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 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:23:20

US3032211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:23:20

US3032211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:53:47

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:23:20

US3032211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:53:47

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:23:20

US3032211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:40
User signature succeeded.	Keith Vrbicky (b) (4)	02 Nov 2020 22:11:27
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 07:50:59
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 14:44:45
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	29 Oct 2020 14:44:34
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 11:38:48
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:34:48
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:18:30

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:53:47

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:56:35
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 04:54:15
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 13:01:08
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	12 Oct 2020 13:01:03
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	12 Oct 2020 13:01:03
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 12:03:58
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:37:18
User entered '166.3' cm	Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:29:35

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:53:47

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:56:35
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	12 Oct 2020 13:01:03
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	12 Oct 2020 13:01:03
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
	(b) (4)	
User entered '102.0' kg	Kelsey Kelley (b) (4)	18 Aug 2020 18:29:35
	(b) (4)	

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:53:47

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:56:35
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 04:54:15
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 13:01:08
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	12 Oct 2020 13:01:03
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	12 Oct 2020 13:01:03
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 12:03:58
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:37:18
User entered '166.3' cm	Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:29:35

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:53:47

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:56:35
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	12 Oct 2020 13:01:03
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	12 Oct 2020 13:01:03
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
	(b) (4)	
User entered '102.0' kg	Kelsey Kelley (b) (4)	18 Aug 2020 18:29:35
	(b) (4)	

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:29:35

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:29:35

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '18 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:29:35

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '11:25'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:29:35

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User entered '18 Aug 2020 11:25'	System	18 Aug 2020 18:29:35

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '36.7' C reason for change: Data Entry Error	System	18 Aug 2020 18:29:51
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Kelsey Kelley (b) (4)	18 Aug 2020 18:29:51
User entered '36.7' (non-conformant).	(b) (4)	
	System	18 Aug 2020 18:29:35
	Kelsey Kelley (b) (4)	18 Aug 2020 18:29:35
	(b) (4)	

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:29:35

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:29:35

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '71'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:29:35

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User entered 'bpm'	System	18 Aug 2020 18:29:35

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '16'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:29:35

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User entered 'breaths/min'	System	18 Aug 2020 18:29:35

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '126'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:29:35

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User entered 'mmHg'	System	18 Aug 2020 18:29:35

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '73'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:29:35

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User entered 'mmHg'	System	18 Aug 2020 18:29:35

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:53:47

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.	(b) (4)	17 Dec 2020 18:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:56:35
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 04:54:15
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 13:01:08
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	12 Oct 2020 13:01:03
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	12 Oct 2020 13:01:03
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 12:03:58
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:37:18
User entered '166.3' cm	Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:29:35

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:53:47

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:56:35
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	12 Oct 2020 13:01:03
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	12 Oct 2020 13:01:03
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
	(b) (4)	
User entered '102.0' kg	Kelsey Kelley (b) (4)	18 Aug 2020 18:29:35
	(b) (4)	

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:29:51

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Aug 2020 18:30:39
User entered 'Yes (Y)' reason for change: Data Entry Error	System	18 Aug 2020 18:30:39
User opened query 'Data is required. Please complete.' (Site from System).	Kelsey Kelley (b) (4)	18 Aug 2020 18:30:39
User entered empty.	(b) (4)	
	System	18 Aug 2020 18:29:51
	Kelsey Kelley (b) (4)	18 Aug 2020 18:29:51
	(b) (4)	

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '18 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	18 Aug 2020 18:30:39
User entered empty.	(b) (4)	
	Kelsey Kelley (b) (4)	18 Aug 2020 18:29:51
	(b) (4)	

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
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)	19 Aug 2020 14:25:31
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 Minutes per current protocol' (Site from System).	Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:30:48
User opened 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).		18 Aug 2020 18:30:39
User entered '13:00' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:30:39
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:29:51

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User entered '18 Aug 2020 13:00'	System	18 Aug 2020 18:30:39
User entered empty.	System	18 Aug 2020 18:29:51

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '36.8' C reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	18 Aug 2020 18:30:39
User entered empty.	(b) (4)	
	Kelsey Kelley (b) (4)	18 Aug 2020 18:29:51
	(b) (4)	

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	18 Aug 2020 18:30:39
User entered empty.	(b) (4)	
	Kelsey Kelley (b) (4)	18 Aug 2020 18:29:51
	(b) (4)	

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:29:51

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '68' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	18 Aug 2020 18:30:39
User entered empty.	(b) (4)	
	Kelsey Kelley (b) (4)	18 Aug 2020 18:29:51
	(b) (4)	

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User entered 'bpm'	System	18 Aug 2020 18:30:39
User entered empty.	System	18 Aug 2020 18:29:51

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '16' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	18 Aug 2020 18:30:39
User entered empty.	(b) (4)	
	Kelsey Kelley (b) (4)	18 Aug 2020 18:29:51
	(b) (4)	

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User entered 'breaths/min'	System	18 Aug 2020 18:30:39
User entered empty.	System	18 Aug 2020 18:29:51

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '120' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	18 Aug 2020 18:30:39
User entered empty.	(b) (4)	
	Kelsey Kelley (b) (4)	18 Aug 2020 18:29:51
	(b) (4)	

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User entered 'mmHg'	System	18 Aug 2020 18:30:39
User entered empty.	System	18 Aug 2020 18:29:51

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '73' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	18 Aug 2020 18:30:39
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	18 Aug 2020 18:29:51
	(b) (4)	

US3032211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User entered 'mmHg'	System	18 Aug 2020 18:30:39
User entered empty.	System	18 Aug 2020 18:29:51

US3032211

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 21:53:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:49
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:23:38

US3032211

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 21:53:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:49
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '18 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:23:38

US3032211

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 16:37:46
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 08:11:24
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 17:07:23
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	23 Oct 2020 17:07:17
User entered 'No (N)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	23 Oct 2020 17:07:17
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 11:57:43
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:37:18
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:28:11

US3032211

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 16:37:46
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	23 Oct 2020 17:07:17
	(b) (4)	
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4)	23 Oct 2020 17:07:17
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
	(b) (4)	
User entered '18 Aug 2020'	Kelsey Kelley (b) (4)	18 Aug 2020 18:28:11
	(b) (4)	

US3032211

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 16:37:46
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	23 Oct 2020 17:07:17
	(b) (4)	
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4)	23 Oct 2020 17:07:17
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
	(b) (4)	
User entered 'Urine (URINE)'	Kelsey Kelley (b) (4)	18 Aug 2020 18:28:11
	(b) (4)	

US3032211

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 16:37:46
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	23 Oct 2020 17:07:17
	(b) (4)	
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4)	23 Oct 2020 17:07:17
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
	(b) (4)	
User entered 'Negative (NEGATIVE)'	Kelsey Kelley (b) (4)	18 Aug 2020 18:28:11
	(b) (4)	

US3032211

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:30:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 16:37:46
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 10:02:08
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 13:24:58
User entered 'No (N)' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	27 Oct 2020 13:24:53
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 08:11:29
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	23 Oct 2020 17:07:17
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	23 Oct 2020 17:07:17
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:37:18
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:28:11

US3032211

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:28:11

US3032211

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:30:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:28:11

US3032211

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User entered empty.	System	18 Aug 2020 18:28:11

US3032211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:31:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Aug 2020 17:41:19

US3032211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:31:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4)	
	Linden DeBoer (b) (4)	18 Aug 2020 17:41:19
	(b) (4)	

US3032211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

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 19:15:06
DataPoint Verified.		17 Dec 2020 18:31:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Aug 2020 17:41:19

US3032211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User entered 'MRNA-1273 OR PLACEBO'	System	18 Aug 2020 17:41:19

US3032211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:31:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '18 Aug 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Aug 2020 17:41:19

US3032211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:31:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '12:25'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Aug 2020 17:41:19

US3032211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User entered '18 Aug 2020 12:25'	System	18 Aug 2020 17:41:19

US3032211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:31:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Left Arm (LEFT ARM)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Aug 2020 17:41:19

US3032211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:31:21
User entered 'ONCE'	System	18 Aug 2020 17:41:19

US3032211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User entered 'INTRAMUSCULAR'	System	18 Aug 2020 17:41:19

US3032211

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:31:38
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:32:14

US3032211

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:31:38
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '18 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:32:14

US3032211

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:31:38
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
	(b) (4)	
User entered '11:45' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	04 Dec 2020 15:36:05
	(b) (4)	
Signature has been broken.	Samantha Wieseler (b) (4)	04 Dec 2020 15:35:44
	(b) (4)	
User entered '14:02' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	04 Dec 2020 15:35:44
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
	(b) (4)	
User entered '11:45'	Kelsey Kelley (b) (4)	18 Aug 2020 18:32:14
	(b) (4)	

US3032211

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User entered '18 Aug 2020 11:45'	System	04 Dec 2020 15:36:05
User entered '18 Aug 2020 14:02'	System	04 Dec 2020 15:35:44
User entered '18 Aug 2020 11:45'	System	18 Aug 2020 18:32:14

US3032211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 21:53:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:31:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '18 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:32:24

US3032211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:53:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:32:24

US3032211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:53:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:31:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:32:24

US3032211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:31:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '11:36'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:32:24

US3032211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User entered '18 Aug 2020 11:36'	System	18 Aug 2020 18:32:24

US3032211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:53:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:32:24

US3032211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:53:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:31:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:32:24

US3032211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:53:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:31:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:32:24

US3032211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User entered empty.	System	18 Aug 2020 18:32:24

US3032211

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:31:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:32:27

US3032211

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User entered '1'	System	18 Aug 2020 18:32:27

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
Data entry locked.	System	18 Aug 2020 17:41:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:53:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-18T12:59:26', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'a2ba507b-06fd-47a0-bade-223340e58727' User entered 'Yes (Y)'	System	18 Aug 2020 18:00:09
	System	18 Aug 2020 18:00:09

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:53:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-18T12:59:32', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'a2ba507b-06fd-47a0-bade-223340e58727' User entered '98.2'	System	18 Aug 2020 18:00:09
	System	18 Aug 2020 18:00:09

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-18T12:59:59', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'a2ba507b-06fd-47a0-bade-223340e58727'	System	18 Aug 2020 18:00:09
User entered 'No (N)'	System	18 Aug 2020 18:00:09

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:53:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-18T13:00:06', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'a2ba507b-06fd-47a0-bade-223340e58727'	System	18 Aug 2020 18:00:09
User entered '18 Aug 2020 13:00'	System	18 Aug 2020 18:00:09

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:53:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '18 Aug 2020 12:45'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:53:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '18 Aug 2020 15:15'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
Data entry locked.	System	18 Aug 2020 17:41:19
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:53:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-18T16:55:42', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '48410854-5510-46c0-be0e-90162e325616' User entered 'Yes (Y)'	System	18 Aug 2020 21:58:14
	System	18 Aug 2020 21:58:14

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:53:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-18T16:58:02', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '48410854-5510-46c0-be0e-90162e325616' User entered '98.3'	System	18 Aug 2020 21:58:14
	System	18 Aug 2020 21:58:14

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-18T16:58:05', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '48410854-5510-46c0-be0e-90162e325616'	System	18 Aug 2020 21:58:14
User entered 'No (N)'	System	18 Aug 2020 21:58:14

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:53:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-18T16:58:11', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '48410854-5510-46c0-be0e-90162e325616'	System	18 Aug 2020 21:58:14
User entered '18 Aug 2020 16:58'	System	18 Aug 2020 21:58:14

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:53:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '18 Aug 2020 16:10'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:53:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
Data entry locked.	System	18 Aug 2020 17:41:19
User entered 'Day 2'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:53:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-19T12:05:17', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '0560b117-fd7c-49ea-aff2-559d31fb1c4c' User entered 'Yes (Y)'	System	19 Aug 2020 17:05:38
	System	19 Aug 2020 17:05:38

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:53:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-19T12:05:21', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '0560b117-fd7c-49ea-aff2-559d31fb1c4c' User entered '97.8'	System	19 Aug 2020 17:05:38
	System	19 Aug 2020 17:05:38

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-19T12:05:25', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '0560b117-fd7c-49ea-aff2-559d31fb1c4c'	System	19 Aug 2020 17:05:38
User entered 'No (N)'	System	19 Aug 2020 17:05:38

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:53:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-19T12:05:31', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '0560b117-fd7c-49ea-aff2-559d31fb1c4c'	System	19 Aug 2020 17:05:38
User entered '19 Aug 2020 12:05'	System	19 Aug 2020 17:05:38

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:53:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:53:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
Data entry locked.	System	18 Aug 2020 17:41:19
User entered 'Day 3'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:53:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-20T17:26:41', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'f926706a-7a8b-49de-b4e2-d878a1b61edd' User entered 'Yes (Y)'	System	20 Aug 2020 22:26:57
	System	20 Aug 2020 22:26:57

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:53:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-20T17:26:45', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'f926706a-7a8b-49de-b4e2-d878a1b61edd' User entered '98.6'	System	20 Aug 2020 22:26:57
	System	20 Aug 2020 22:26:57

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-20T17:26:49', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'f926706a-7a8b-49de-b4e2-d878a1b61edd' User entered 'No (N)'	System	20 Aug 2020 22:26:57
	System	20 Aug 2020 22:26:57

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:53:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-20T17:26:54', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'f926706a-7a8b-49de-b4e2-d878a1b61edd' User entered '20 Aug 2020 17:26'	System	20 Aug 2020 22:26:57
	System	20 Aug 2020 22:26:57

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:53:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:53:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
Data entry locked.	System	18 Aug 2020 17:41:19
User entered 'Day 4'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:53:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-21T12:29:38', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'b69eee53-df39-4f16-8eff-8e37056b2cbc' User entered 'Yes (Y)'	System	21 Aug 2020 17:29:50
	System	21 Aug 2020 17:29:50

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:53:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-21T12:29:42', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'b69eee53-df39-4f16-8eff-8e37056b2cbc' User entered '98.5'	System	21 Aug 2020 17:29:50
	System	21 Aug 2020 17:29:50

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-21T12:29:45', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'b69eee53-df39-4f16-8eff-8e37056b2cbc'	System	21 Aug 2020 17:29:50
User entered 'No (N)'	System	21 Aug 2020 17:29:50

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:53:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-21T12:29:48', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'b69eee53-df39-4f16-8eff-8e37056b2cbc' User entered '21 Aug 2020 12:29'	System	21 Aug 2020 17:29:50
	System	21 Aug 2020 17:29:50

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:53:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:53:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
Data entry locked.	System	18 Aug 2020 17:41:19
User entered 'Day 5'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:53:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-22T16:46:24', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '1a82c3ab-e7af-4e7d-813c-2965cd12a504' User entered 'Yes (Y)'	System	22 Aug 2020 21:46:36
	System	22 Aug 2020 21:46:36

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:53:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-22T16:46:28', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '1a82c3ab-e7af-4e7d-813c-2965cd12a504' User entered '97.2'	System	22 Aug 2020 21:46:36
	System	22 Aug 2020 21:46:36

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-22T16:46:31', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '1a82c3ab-e7af-4e7d-813c-2965cd12a504'	System	22 Aug 2020 21:46:36
User entered 'No (N)'	System	22 Aug 2020 21:46:36

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:53:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-22T16:46:33', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '1a82c3ab-e7af-4e7d-813c-2965cd12a504' User entered '22 Aug 2020 16:46'	System	22 Aug 2020 21:46:36
	System	22 Aug 2020 21:46:36

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:53:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:53:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
Data entry locked.	System	18 Aug 2020 17:41:19
User entered 'Day 6'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:53:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-23T15:14:12', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'b08581a6-3b29-461f-803e-e16d63d6060f' User entered 'Yes (Y)'	System	23 Aug 2020 20:14:28
	System	23 Aug 2020 20:14:28

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:53:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-23T15:14:16', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'b08581a6-3b29-461f-803e-e16d63d6060f' User entered '97.3'	System	23 Aug 2020 20:14:28
	System	23 Aug 2020 20:14:28

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-23T15:14:20', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'b08581a6-3b29-461f-803e-e16d63d6060f' User entered 'No (N)'	System	23 Aug 2020 20:14:28
	System	23 Aug 2020 20:14:28

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:53:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-23T15:14:22', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'b08581a6-3b29-461f-803e-e16d63d6060f' User entered '23 Aug 2020 15:14'	System	23 Aug 2020 20:14:28
	System	23 Aug 2020 20:14:28

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:53:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:53:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
Data entry locked.	System	18 Aug 2020 17:41:19
User entered 'Day 7'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:53:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-24T13:35:42', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'bcfcc803-61f5-46d0-abcd-5f3c15718496'	System	24 Aug 2020 18:35:54
User entered 'Yes (Y)'	System	24 Aug 2020 18:35:54

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:53:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-24T13:35:47', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'bcfcc803-61f5-46d0-abcd-5f3c15718496' User entered '97.5'	System	24 Aug 2020 18:35:54
	System	24 Aug 2020 18:35:54

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-24T13:35:50', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'bcfcc803-61f5-46d0-abcd-5f3c15718496'	System	24 Aug 2020 18:35:54
User entered 'No (N)'	System	24 Aug 2020 18:35:54

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:53:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-24T13:35:52', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'bcfcc803-61f5-46d0-abcd-5f3c15718496'	System	24 Aug 2020 18:35:54
User entered '24 Aug 2020 13:35'	System	24 Aug 2020 18:35:54

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:53:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:53:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
Data entry locked.	System	18 Aug 2020 17:41:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:53:47

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 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-18T13:00:37', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'edcaf895-d265-48af-b653-f3fa5c5eec17'	System	18 Aug 2020 18:01:48
User entered 'None (1)'	System	18 Aug 2020 18:01:48

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:53:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-18T13:00:40', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'edcaf895-d265-48af-b653-f3fa5c5eec17'	System	18 Aug 2020 18:01:48
User entered 'No (N)'	System	18 Aug 2020 18:01:48

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-18T13:00:46', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'edcaf895-d265-48af-b653-f3fa5c5eec17'	System	18 Aug 2020 18:01:48
User entered 'No (N)'	System	18 Aug 2020 18:01:48

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:53:47

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 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-18T13:00:52', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'edcaf895-d265-48af-b653-f3fa5c5eec17'	System	18 Aug 2020 18:01:48
User entered 'None (1)'	System	18 Aug 2020 18:01:48

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:53:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-18T13:00:55', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'edcaf895-d265-48af-b653-f3fa5c5eec17'	System	18 Aug 2020 18:01:48
User entered '18 Aug 2020 13:00'	System	18 Aug 2020 18:01:48

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:53:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '18 Aug 2020 12:45'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:53:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '18 Aug 2020 15:15'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
Data entry locked.	System	18 Aug 2020 17:41:19
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:53:47

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 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-18T16:58:19', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'f9deabd2-aaab-48e4-ba3f-0b6d99f2088d' User entered 'Does not interfere with activity (2)'	System	18 Aug 2020 21:58:43
	System	18 Aug 2020 21:58:43

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:53:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-18T16:58:22', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'f9deabd2-aaab-48e4-ba3f-0b6d99f2088d' User entered 'No (N)'	System	18 Aug 2020 21:58:43
	System	18 Aug 2020 21:58:43

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-18T16:58:29', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'f9deabd2-aaab-48e4-ba3f-0b6d99f2088d' User entered 'No (N)'	System	18 Aug 2020 21:58:43
	System	18 Aug 2020 21:58:43

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:53:47

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 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-18T16:58:37', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'f9deabd2-aaab-48e4-ba3f-0b6d99f2088d'	System	18 Aug 2020 21:58:43
User entered 'None (1)'	System	18 Aug 2020 21:58:43

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:53:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-18T16:58:40', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'f9deabd2-aaab-48e4-ba3f-0b6d99f2088d' User entered '18 Aug 2020 16:58'	System	18 Aug 2020 21:58:43
	System	18 Aug 2020 21:58:43

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:53:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '18 Aug 2020 16:10'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:53:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
Data entry locked.	System	18 Aug 2020 17:41:19
User entered 'Day 2'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:53:47

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 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-19T12:05:42', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'a1c2369a-745c-486b-861b-b011e1c071a7' User entered 'None (1)'	System	19 Aug 2020 17:06:19
	System	19 Aug 2020 17:06:19

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:53:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-19T12:05:54', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'a1c2369a-745c-486b-861b-b011e1c071a7' User entered 'No (N)'	System	19 Aug 2020 17:06:19
	System	19 Aug 2020 17:06:19

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-19T12:06:11', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'a1c2369a-745c-486b-861b-b011e1c071a7' User entered 'No (N)'	System	19 Aug 2020 17:06:19
	System	19 Aug 2020 17:06:19

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:53:47

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 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-19T12:06:14', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'a1c2369a-745c-486b-861b-b011e1c071a7' User entered 'None (1)'	System	19 Aug 2020 17:06:19
	System	19 Aug 2020 17:06:19

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:53:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-19T12:06:17', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'a1c2369a-745c-486b-861b-b011e1c071a7' User entered '19 Aug 2020 12:06'	System	19 Aug 2020 17:06:19
	System	19 Aug 2020 17:06:19

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:53:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:53:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
Data entry locked.	System	18 Aug 2020 17:41:19
User entered 'Day 3'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:53:47

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 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-20T17:26:58', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '7fe30511-6fc6-46a2-a8d1-dfc781f602a6'	System	20 Aug 2020 22:27:31
User entered 'None (1)'	System	20 Aug 2020 22:27:31

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:53:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-20T17:27:07', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '7fe30511-6fc6-46a2-a8d1-dfc781f602a6' User entered 'No (N)'	System	20 Aug 2020 22:27:31
	System	20 Aug 2020 22:27:31

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-20T17:27:20', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '7fe30511-6fc6-46a2-a8d1-dfc781f602a6' User entered 'No (N)'	System	20 Aug 2020 22:27:31
	System	20 Aug 2020 22:27:31

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:53:47

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 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-20T17:27:25', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '7fe30511-6fc6-46a2-a8d1-dfc781f602a6'	System	20 Aug 2020 22:27:31
User entered 'None (1)'	System	20 Aug 2020 22:27:31

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:53:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-20T17:27:28', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '7fe30511-6fc6-46a2-a8d1-dfc781f602a6' User entered '20 Aug 2020 17:27'	System	20 Aug 2020 22:27:31
	System	20 Aug 2020 22:27:31

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:53:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:53:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
Data entry locked.	System	18 Aug 2020 17:41:19
User entered 'Day 4'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:53:47

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 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-21T12:29:51', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '3f72f304-9933-48f1-9f3c-2be38f0d1b55'	System	21 Aug 2020 17:30:27
User entered 'None (1)'	System	21 Aug 2020 17:30:27

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:53:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-21T12:29:59', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '3f72f304-9933-48f1-9f3c-2be38f0d1b55'	System	21 Aug 2020 17:30:27
User entered 'No (N)'	System	21 Aug 2020 17:30:27

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-21T12:30:10', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '3f72f304-9933-48f1-9f3c-2be38f0d1b55'	System	21 Aug 2020 17:30:27
User entered 'No (N)'	System	21 Aug 2020 17:30:27

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:53:47

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 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-21T12:30:21', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '3f72f304-9933-48f1-9f3c-2be38f0d1b55'	System	21 Aug 2020 17:30:27
User entered 'None (1)'	System	21 Aug 2020 17:30:27

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:53:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-21T12:30:24', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '3f72f304-9933-48f1-9f3c-2be38f0d1b55'	System	21 Aug 2020 17:30:27
User entered '21 Aug 2020 12:30'	System	21 Aug 2020 17:30:27

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:53:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:53:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
Data entry locked.	System	18 Aug 2020 17:41:19
User entered 'Day 5'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:53:47

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 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-22T16:46:38', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '04055b6d-124f-4204-a699-e2d92a9c78a3'	System	22 Aug 2020 21:46:52
User entered 'None (1)'	System	22 Aug 2020 21:46:52

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:53:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-22T16:46:40', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '04055b6d-124f-4204-a699-e2d92a9c78a3' User entered 'No (N)'	System	22 Aug 2020 21:46:52
	System	22 Aug 2020 21:46:52

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-22T16:46:42', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '04055b6d-124f-4204-a699-e2d92a9c78a3' User entered 'No (N)'	System	22 Aug 2020 21:46:52
	System	22 Aug 2020 21:46:52

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:53:47

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 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-22T16:46:45', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '04055b6d-124f-4204-a699-e2d92a9c78a3' User entered 'None (1)'	System	22 Aug 2020 21:46:52
	System	22 Aug 2020 21:46:52

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:53:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-22T16:46:50', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '04055b6d-124f-4204-a699-e2d92a9c78a3' User entered '22 Aug 2020 16:46'	System	22 Aug 2020 21:46:52
	System	22 Aug 2020 21:46:52

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:53:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:53:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
Data entry locked.	System	18 Aug 2020 17:41:19
User entered 'Day 6'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:53:47

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 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-23T15:14:27', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'a259ff96-bd92-4af8-80ae-4b09fbf0c218'	System	23 Aug 2020 20:14:47
User entered 'None (1)'	System	23 Aug 2020 20:14:47

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:53:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-23T15:14:30', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'a259ff96-bd92-4af8-80ae-4b09fbf0c218'	System	23 Aug 2020 20:14:47
User entered 'No (N)'	System	23 Aug 2020 20:14:47

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-23T15:14:36', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'a259ff96-bd92-4af8-80ae-4b09fbf0c218'	System	23 Aug 2020 20:14:47
User entered 'No (N)'	System	23 Aug 2020 20:14:47

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:53:47

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 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-23T15:14:43', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'a259ff96-bd92-4af8-80ae-4b09fbf0c218'	System	23 Aug 2020 20:14:47
User entered 'None (1)'	System	23 Aug 2020 20:14:47

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:53:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-23T15:14:45', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'a259ff96-bd92-4af8-80ae-4b09fbf0c218'	System	23 Aug 2020 20:14:47
User entered '23 Aug 2020 15:14'	System	23 Aug 2020 20:14:47

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:53:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:53:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
Data entry locked.	System	18 Aug 2020 17:41:19
User entered 'Day 7'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:53:47

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 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-24T13:35:55', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '07e70700-5e1b-4de1-8821-c3ea5f0e101e' User entered 'None (1)'	System	24 Aug 2020 18:36:12
	System	24 Aug 2020 18:36:12

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:53:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-24T13:35:59', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '07e70700-5e1b-4de1-8821-c3ea5f0e101e' User entered 'No (N)'	System	24 Aug 2020 18:36:12
	System	24 Aug 2020 18:36:12

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-24T13:36:01', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '07e70700-5e1b-4de1-8821-c3ea5f0e101e' User entered 'No (N)'	System	24 Aug 2020 18:36:12
	System	24 Aug 2020 18:36:12

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:53:47

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 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-24T13:36:03', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '07e70700-5e1b-4de1-8821-c3ea5f0e101e' User entered 'None (1)'	System	24 Aug 2020 18:36:12
	System	24 Aug 2020 18:36:12

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:53:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-24T13:36:05', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '07e70700-5e1b-4de1-8821-c3ea5f0e101e' User entered '24 Aug 2020 13:36'	System	24 Aug 2020 18:36:12
	System	24 Aug 2020 18:36:12

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:53:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:53:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
Data entry locked.	System	18 Aug 2020 17:41:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-18T13:01:02', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '3a173324-7352-465b-a09f-44a718446590' User entered 'None (0)'	System	18 Aug 2020 18:01:55
	System	18 Aug 2020 18:01:55

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-18T13:01:08', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '3a173324-7352-465b-a09f-44a718446590' User entered 'None (0)'	System	18 Aug 2020 18:01:55
	System	18 Aug 2020 18:01:55

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-18T13:01:13', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '3a173324-7352-465b-a09f-44a718446590' User entered 'None (0)'	System	18 Aug 2020 18:01:55
	System	18 Aug 2020 18:01:55

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-18T13:01:18', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '3a173324-7352-465b-a09f-44a718446590' User entered 'None (0)'	System	18 Aug 2020 18:01:55
	System	18 Aug 2020 18:01:55

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-18T13:01:20', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '3a173324-7352-465b-a09f-44a718446590' User entered 'None (0)'	System	18 Aug 2020 18:01:55
	System	18 Aug 2020 18:01:55

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-18T13:01:22', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '3a173324-7352-465b-a09f-44a718446590' User entered 'None (0)'	System	18 Aug 2020 18:01:55
	System	18 Aug 2020 18:01:55

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:47

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 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-18T13:01:30', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '3a173324-7352-465b-a09f-44a718446590' User entered 'No (N)'	System	18 Aug 2020 18:01:55
	System	18 Aug 2020 18:01:55

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-18T13:01:32', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '3a173324-7352-465b-a09f-44a718446590' User entered '18 Aug 2020 13:01'	System	18 Aug 2020 18:01:55
	System	18 Aug 2020 18:01:55

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '18 Aug 2020 12:45'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '18 Aug 2020 15:15'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
Data entry locked.	System	18 Aug 2020 17:41:19
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-18T16:58:44', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '185722d5-5824-4bd2-b72b-408112d8d289' User entered 'None (0)'	System	18 Aug 2020 21:59:23
	System	18 Aug 2020 21:59:23

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-18T16:58:51', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '185722d5-5824-4bd2-b72b-408112d8d289' User entered 'None (0)'	System	18 Aug 2020 21:59:23
	System	18 Aug 2020 21:59:23

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-18T16:58:55', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '185722d5-5824-4bd2-b72b-408112d8d289' User entered 'None (0)'	System	18 Aug 2020 21:59:23
	System	18 Aug 2020 21:59:23

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-18T16:58:58', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '185722d5-5824-4bd2-b72b-408112d8d289' User entered 'None (0)'	System	18 Aug 2020 21:59:23
	System	18 Aug 2020 21:59:23

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-18T16:59:06', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '185722d5-5824-4bd2-b72b-408112d8d289' User entered 'None (0)'	System	18 Aug 2020 21:59:23
	System	18 Aug 2020 21:59:23

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-18T16:59:09', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '185722d5-5824-4bd2-b72b-408112d8d289' User entered 'None (0)'	System	18 Aug 2020 21:59:23
	System	18 Aug 2020 21:59:23

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:47

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 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-18T16:59:19', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '185722d5-5824-4bd2-b72b-408112d8d289'	System	18 Aug 2020 21:59:23
User entered 'No (N)'	System	18 Aug 2020 21:59:23

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-18T16:59:22', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '185722d5-5824-4bd2-b72b-408112d8d289' User entered '18 Aug 2020 16:59'	System	18 Aug 2020 21:59:23
	System	18 Aug 2020 21:59:23

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '18 Aug 2020 16:10'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
Data entry locked.	System	18 Aug 2020 17:41:19
User entered 'Day 2'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-19T12:06:21', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'a1763d7d-f962-4466-b3a4-4ef50b12f767' User entered 'None (0)'	System	19 Aug 2020 17:06:44
	System	19 Aug 2020 17:06:44

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-19T12:06:25', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'a1763d7d-f962-4466-b3a4-4ef50b12f767' User entered 'None (0)'	System	19 Aug 2020 17:06:44
	System	19 Aug 2020 17:06:44

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-19T12:06:27', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'a1763d7d-f962-4466-b3a4-4ef50b12f767' User entered 'None (0)'	System	19 Aug 2020 17:06:44
	System	19 Aug 2020 17:06:44

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-19T12:06:30', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'a1763d7d-f962-4466-b3a4-4ef50b12f767' User entered 'None (0)'	System	19 Aug 2020 17:06:44
	System	19 Aug 2020 17:06:44

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-19T12:06:33', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'a1763d7d-f962-4466-b3a4-4ef50b12f767' User entered 'None (0)'	System	19 Aug 2020 17:06:44
	System	19 Aug 2020 17:06:44

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-19T12:06:34', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'a1763d7d-f962-4466-b3a4-4ef50b12f767' User entered 'None (0)'	System	19 Aug 2020 17:06:44
	System	19 Aug 2020 17:06:44

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:47

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 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-19T12:06:40', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'a1763d7d-f962-4466-b3a4-4ef50b12f767' User entered 'No (N)'	System	19 Aug 2020 17:06:44
	System	19 Aug 2020 17:06:44

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-19T12:06:42', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'a1763d7d-f962-4466-b3a4-4ef50b12f767'	System	19 Aug 2020 17:06:44
User entered '19 Aug 2020 12:06'	System	19 Aug 2020 17:06:44

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
Data entry locked.	System	18 Aug 2020 17:41:19
User entered 'Day 3'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-20T17:27:33', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '5c060578-baf2-44fe-b3cb-03fdf02c82df' User entered 'None (0)'	System	20 Aug 2020 22:27:56
	System	20 Aug 2020 22:27:56

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-20T17:27:36', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '5c060578-baf2-44fe-b3cb-03fdf02c82df' User entered 'None (0)'	System	20 Aug 2020 22:27:56
	System	20 Aug 2020 22:27:56

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-20T17:27:38', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '5c060578-baf2-44fe-b3cb-03fdf02c82df' User entered 'None (0)'	System	20 Aug 2020 22:27:56
	System	20 Aug 2020 22:27:56

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-20T17:27:40', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '5c060578-baf2-44fe-b3cb-03fdf02c82df' User entered 'None (0)'	System	20 Aug 2020 22:27:56
	System	20 Aug 2020 22:27:56

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-20T17:27:42', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '5c060578-baf2-44fe-b3cb-03fdf02c82df' User entered 'None (0)'	System	20 Aug 2020 22:27:56
	System	20 Aug 2020 22:27:56

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-20T17:27:45', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '5c060578-baf2-44fe-b3cb-03fdf02c82df' User entered 'None (0)'	System	20 Aug 2020 22:27:56
	System	20 Aug 2020 22:27:56

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:47

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 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-20T17:27:52', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '5c060578-baf2-44fe-b3cb-03fdf02c82df' User entered 'No (N)'	System	20 Aug 2020 22:27:56
	System	20 Aug 2020 22:27:56

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-20T17:27:55', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '5c060578-baf2-44fe-b3cb-03fdf02c82df' User entered '20 Aug 2020 17:27'	System	20 Aug 2020 22:27:56
	System	20 Aug 2020 22:27:56

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
Data entry locked.	System	18 Aug 2020 17:41:19
User entered 'Day 4'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-21T12:30:27', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'b1bf0f9b-3018-408e-9517-2f1ab6bf4eea' User entered 'None (0)'	System	21 Aug 2020 17:30:53
	System	21 Aug 2020 17:30:53

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-21T12:30:29', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'b1bf0f9b-3018-408e-9517-2f1ab6bf4eea' User entered 'None (0)'	System	21 Aug 2020 17:30:53
	System	21 Aug 2020 17:30:53

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-21T12:30:31', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'b1bf0f9b-3018-408e-9517-2f1ab6bf4eea' User entered 'None (0)'	System	21 Aug 2020 17:30:53
	System	21 Aug 2020 17:30:53

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-21T12:30:34', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'b1bf0f9b-3018-408e-9517-2f1ab6bf4eea' User entered 'None (0)'	System	21 Aug 2020 17:30:53
	System	21 Aug 2020 17:30:53

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-21T12:30:36', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'b1bf0f9b-3018-408e-9517-2f1ab6bf4eea' User entered 'None (0)'	System	21 Aug 2020 17:30:53
	System	21 Aug 2020 17:30:53

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-21T12:30:38', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'b1bf0f9b-3018-408e-9517-2f1ab6bf4eea' User entered 'None (0)'	System	21 Aug 2020 17:30:53
	System	21 Aug 2020 17:30:53

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:47

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 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-21T12:30:45', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'b1bf0f9b-3018-408e-9517-2f1ab6bf4eea' User entered 'No (N)'	System	21 Aug 2020 17:30:53
	System	21 Aug 2020 17:30:53

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-21T12:30:48', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'b1bf0f9b-3018-408e-9517-2f1ab6bf4eea' User entered '21 Aug 2020 12:30'	System	21 Aug 2020 17:30:53
	System	21 Aug 2020 17:30:53

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
Data entry locked.	System	18 Aug 2020 17:41:19
User entered 'Day 5'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-22T16:46:53', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'e227cbe9-414d-4139-88f1-40f1265309bd' User entered 'None (0)'	System	22 Aug 2020 21:47:15
	System	22 Aug 2020 21:47:15

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-22T16:46:55', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'e227cbe9-414d-4139-88f1-40f1265309bd' User entered 'None (0)'	System	22 Aug 2020 21:47:15
	System	22 Aug 2020 21:47:15

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-22T16:46:58', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'e227cbe9-414d-4139-88f1-40f1265309bd' User entered 'None (0)'	System	22 Aug 2020 21:47:15
	System	22 Aug 2020 21:47:15

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-22T16:46:59', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'e227cbe9-414d-4139-88f1-40f1265309bd' User entered 'None (0)'	System	22 Aug 2020 21:47:15
	System	22 Aug 2020 21:47:15

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-22T16:47:01', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'e227cbe9-414d-4139-88f1-40f1265309bd' User entered 'None (0)'	System	22 Aug 2020 21:47:15
	System	22 Aug 2020 21:47:15

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-22T16:47:03', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'e227cbe9-414d-4139-88f1-40f1265309bd' User entered 'None (0)'	System	22 Aug 2020 21:47:15
	System	22 Aug 2020 21:47:15

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:47

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 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-22T16:47:09', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'e227cbe9-414d-4139-88f1-40f1265309bd' User entered 'No (N)'	System	22 Aug 2020 21:47:15
	System	22 Aug 2020 21:47:15

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-22T16:47:11', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'e227cbe9-414d-4139-88f1-40f1265309bd' User entered '22 Aug 2020 16:47'	System	22 Aug 2020 21:47:15
	System	22 Aug 2020 21:47:15

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
Data entry locked.	System	18 Aug 2020 17:41:19
User entered 'Day 6'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-23T15:14:49', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '0e00096d-5de8-4323-942b-f6fe7aa853a5' User entered 'None (0)'	System	23 Aug 2020 20:15:06
	System	23 Aug 2020 20:15:06

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-23T15:14:51', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '0e00096d-5de8-4323-942b-f6fe7aa853a5' User entered 'None (0)'	System	23 Aug 2020 20:15:06
	System	23 Aug 2020 20:15:06

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-23T15:14:52', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '0e00096d-5de8-4323-942b-f6fe7aa853a5' User entered 'None (0)'	System	23 Aug 2020 20:15:06
	System	23 Aug 2020 20:15:06

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-23T15:14:54', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '0e00096d-5de8-4323-942b-f6fe7aa853a5' User entered 'None (0)'	System	23 Aug 2020 20:15:06
	System	23 Aug 2020 20:15:06

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-23T15:14:56', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '0e00096d-5de8-4323-942b-f6fe7aa853a5' User entered 'None (0)'	System	23 Aug 2020 20:15:06
	System	23 Aug 2020 20:15:06

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-23T15:14:57', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '0e00096d-5de8-4323-942b-f6fe7aa853a5' User entered 'None (0)'	System	23 Aug 2020 20:15:06
	System	23 Aug 2020 20:15:06

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:47

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 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-23T15:15:02', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '0e00096d-5de8-4323-942b-f6fe7aa853a5' User entered 'No (N)'	System	23 Aug 2020 20:15:06
	System	23 Aug 2020 20:15:06

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-23T15:15:04', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '0e00096d-5de8-4323-942b-f6fe7aa853a5' User entered '23 Aug 2020 15:15'	System	23 Aug 2020 20:15:06
	System	23 Aug 2020 20:15:06

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
Data entry locked.	System	18 Aug 2020 17:41:19
User entered 'Day 7'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-24T13:36:08', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '65117840-b9de-4fac-8d83-d248761a8d9c' User entered 'None (0)'	System	24 Aug 2020 18:36:26
	System	24 Aug 2020 18:36:26

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-24T13:36:10', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '65117840-b9de-4fac-8d83-d248761a8d9c' User entered 'None (0)'	System	24 Aug 2020 18:36:26
	System	24 Aug 2020 18:36:26

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-24T13:36:11', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '65117840-b9de-4fac-8d83-d248761a8d9c' User entered 'None (0)'	System	24 Aug 2020 18:36:26
	System	24 Aug 2020 18:36:26

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-24T13:36:14', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '65117840-b9de-4fac-8d83-d248761a8d9c' User entered 'None (0)'	System	24 Aug 2020 18:36:26
	System	24 Aug 2020 18:36:26

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-24T13:36:16', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '65117840-b9de-4fac-8d83-d248761a8d9c' User entered 'None (0)'	System	24 Aug 2020 18:36:26
	System	24 Aug 2020 18:36:26

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-24T13:36:18', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '65117840-b9de-4fac-8d83-d248761a8d9c' User entered 'None (0)'	System	24 Aug 2020 18:36:26
	System	24 Aug 2020 18:36:26

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:47

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 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-24T13:36:19', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '65117840-b9de-4fac-8d83-d248761a8d9c' User entered 'No (N)'	System	24 Aug 2020 18:36:26
	System	24 Aug 2020 18:36:26

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-08-24T13:36:21', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '65117840-b9de-4fac-8d83-d248761a8d9c' User entered '24 Aug 2020 13:36'	System	24 Aug 2020 18:36:26
	System	24 Aug 2020 18:36:26

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 17:41:19

US3032211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 17:41:19

US3032211

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:32:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Sep 2020 23:20:44

US3032211

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:32:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '27 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Sep 2020 23:20:44

US3032211

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:32:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Sep 2020 23:20:44

US3032211

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:32:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Sep 2020 23:20:44

US3032211

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:32:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Sep 2020 23:20:46

US3032211

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User entered 'I'	System	03 Sep 2020 23:20:46

US3032211

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:33:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Sep 2020 23:21:18

US3032211

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:33:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '3 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Sep 2020 23:21:18

US3032211

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:33:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Sep 2020 23:21:18

US3032211

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:33:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Sep 2020 23:21:18

US3032211

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:33:22
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Sep 2020 23:21:20

US3032211

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User entered 'I'	System	03 Sep 2020 23:21:20

US3032211

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:39:34
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:48:47

US3032211

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:39:34
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '10 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:48:47

US3032211

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:39:34
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:48:47

US3032211

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:39:34
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:48:47

US3032211

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:39:38
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:48:52

US3032211

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User entered '1'	System	18 Sep 2020 15:48:52

US3032211

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:40:04
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:49:37

US3032211

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:40:04
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '17 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:49:37

US3032211

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:47

[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 19:15:08
DataPoint Verified.		17 Dec 2020 18:40:04
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:49:37

US3032211

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
User entered 'VISIT2'	System	18 Sep 2020 15:49:37

US3032211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:58:30

US3032211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:40:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:58:30

US3032211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:40:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '17 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:58:30

US3032211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:40:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '08:18'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:58:30

US3032211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
User entered '17 Sep 2020 08:18'	System	18 Sep 2020 15:58:30

US3032211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:40:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '36.7' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:58:30

US3032211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:40:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:58:30

US3032211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:40:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:58:30

US3032211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:40:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '76'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:58:30

US3032211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
User entered 'bpm'	System	18 Sep 2020 15:58:30

US3032211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:40:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '16'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:58:30

US3032211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
User entered 'breaths/min'	System	18 Sep 2020 15:58:30

US3032211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:40:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Signature has been broken.	(b) (4)	
	Samantha Wieseler (b) (4)	04 Dec 2020 15:29:00
	(b) (4)	
User entered '118' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	04 Dec 2020 15:29:00
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
	(b) (4)	
User entered '125'	Kelsey Kelley (b) (4)	18 Sep 2020 15:58:30
	(b) (4)	

US3032211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
User entered 'mmHg'	System	18 Sep 2020 15:58:30

US3032211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:40:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Signature has been broken.	(b) (4)	
	Samantha Wieseler (b) (4)	04 Dec 2020 15:29:00
	(b) (4)	
User entered '86' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	04 Dec 2020 15:29:00
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
	(b) (4)	
User entered '94'	Kelsey Kelley (b) (4)	18 Sep 2020 15:58:30
	(b) (4)	

US3032211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
User entered 'mmHg'	System	18 Sep 2020 15:58:30

US3032211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:58:49

US3032211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:40:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:58:49

US3032211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:40:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:58:49

US3032211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:40:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:58:49

US3032211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
User entered empty.	System	18 Sep 2020 15:58:49

US3032211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:40:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:58:49

US3032211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:40:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:58:49

US3032211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:40:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:58:49

US3032211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:40:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:58:49

US3032211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
User entered empty.	System	18 Sep 2020 15:58:49

US3032211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:40:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:58:49

US3032211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
User entered empty.	System	18 Sep 2020 15:58:49

US3032211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:40:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:58:49

US3032211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
User entered empty.	System	18 Sep 2020 15:58:49

US3032211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:40:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:58:49

US3032211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
User entered empty.	System	18 Sep 2020 15:58:49

US3032211

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:53:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:40:46
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:50:58

US3032211

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:53:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:40:46
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '17 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:50:58

US3032211

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:41:09
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:51:47

US3032211

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:41:09
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	18 Sep 2020 15:52:29
User entered '17 Sep 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	18 Sep 2020 15:52:29
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Sep 2020 15:51:47
User entered empty.	Kelsey Kelley (b) (4)	18 Sep 2020 15:51:47

US3032211

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:41:09
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Urine (URINE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:51:47

US3032211

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:41:09
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Negative (NEGATIVE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:51:47

US3032211

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:41:09
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:51:47

US3032211

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:41:09
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:51:47

US3032211

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:41:09
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:51:47

US3032211

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
User entered empty.	System	18 Sep 2020 15:51:47

US3032211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:41:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:56:08

US3032211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:41:21
User closed query 'Per CDM: If the subject is not going to receive any further IP doses, the Dosing Discontinuation form needs to be completed. Kindly review and update as appropriate. ' (Site from DM).		03 Dec 2020 06:18:37
Query 'Per CDM: If the subject is not going to receive any further IP doses, the Dosing Discontinuation form needs to be completed. Kindly review and update as appropriate. ' answered with 'FORM IS NOW UPDATED' (Site from DM).	Russell Herstein (b) (4) (b) (4)	01 Dec 2020 17:14:03
User opened query 'Per CDM: If the subject is not going to receive any further IP doses, the Dosing Discontinuation form needs to be completed. Kindly review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 08:49:51
User closed query 'Per CDM (re-query): Response noted. The reason for study treatment not given is Confirmed Covid 19, but the Covid assessment form is not completed. Kindly update Covid assessment form. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 05:32:21
Query 'Per CDM (re-query): Response noted. The reason for study treatment not given is Confirmed Covid 19, but the Covid assessment form is not completed. Kindly update Covid assessment form. Thank you.' answered with 'ASSESSMENT FORM UPDATED' (Site from DM).	Russell Herstein (b) (4) (b) (4)	23 Nov 2020 15:46:33
User opened query 'Per CDM (re-query): Response noted. The reason for study treatment not given is Confirmed Covid 19, but the Covid assessment form is not completed. Kindly update Covid assessment form. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 09:26:06
User closed query 'Per CDM : The reason for study treatment not given is Confirmed Covid 19, but the Covid assessment form is not completed. Kindly clarify and update Covid assessment form and dosing discontinuation form accordingly. Thanks ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 09:26:06

US3032211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

If No, reason not given

Audit	User	Time (GMT)
Query 'Per CDM : The reason for study treatment not given is Confirmed Covid 19, but the Covid assessment form is not completed. Kindly clarify and update Covid assessment form and dosing discontinuation form accordingly. Thanks ' answered with 'CHART TO BE CHECKED' (Site from DM).	Russell Herstein (b) (4)	20 Nov 2020 00:31:48
User opened query 'Per CDM : The reason for study treatment not given is Confirmed Covid 19, but the Covid assessment form is not completed. Kindly clarify and update Covid assessment form and dosing discontinuation form accordingly. Thanks ' (Site from DM).	(b) (4)	09 Nov 2020 08:21:43
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Confirmed COVID-19 (COVID)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:56:08

US3032211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

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 19:15:08
DataPoint Verified.		17 Dec 2020 18:41:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:56:08

US3032211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
User entered empty.	System	18 Sep 2020 15:56:08

US3032211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:41:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:56:08

US3032211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:41:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:56:08

US3032211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
User entered empty.	System	18 Sep 2020 15:56:08

US3032211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:41:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:56:08

US3032211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:41:21
User entered empty.	System	18 Sep 2020 15:56:08

US3032211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
User entered empty.	System	18 Sep 2020 15:56:08

US3032211

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:41:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 16:00:17

US3032211

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:41:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '17 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 16:00:17

US3032211

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:41:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '08:44'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 16:00:17

US3032211

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
User entered '17 Sep 2020 08:44'	System	18 Sep 2020 16:00:17

US3032211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:44:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '17 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 16:00:30

US3032211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:53:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 16:00:30

US3032211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:53:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:44:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 16:00:30

US3032211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:53:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:44:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '08:36'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 16:00:30

US3032211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User entered '17 Sep 2020 08:36'	System	18 Sep 2020 16:00:30

US3032211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:53:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 16:00:30

US3032211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:53:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:44:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 16:00:30

US3032211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:53:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:44:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 16:00:30

US3032211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User entered empty.	System	18 Sep 2020 16:00:30

US3032211

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:45:10
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 16:00:54

US3032211

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
User entered '1'	System	18 Sep 2020 16:00:54

US3032211

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:46:56
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Signature has been broken.	(b) (4)	
	Samantha Wieseler (b) (4)	04 Dec 2020 15:32:05
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	04 Dec 2020 15:32:05
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:56:35
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	08 Oct 2020 21:51:22
	(b) (4)	

US3032211

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:46:56
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Signature has been broken.	(b) (4)	
	Samantha Wieseler (b) (4)	04 Dec 2020 15:32:05
	(b) (4)	
User entered empty; reason for change Data Entry Error	Samantha Wieseler (b) (4)	04 Dec 2020 15:32:05
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:56:35
	(b) (4)	
User entered '1 Oct 2020'	Kelsey Kelley (b) (4)	08 Oct 2020 21:51:22
	(b) (4)	

US3032211

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:46:56
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Signature has been broken.	(b) (4)	
	Samantha Wieseler (b) (4)	04 Dec 2020 15:32:05
	(b) (4)	
User entered empty; reason for change Data Entry Error	Samantha Wieseler (b) (4)	04 Dec 2020 15:32:05
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:56:35
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Kelsey Kelley (b) (4)	08 Oct 2020 21:51:22
	(b) (4)	

US3032211

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:46:56
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:56:35
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 21:51:22

US3032211

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:46:40
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:56:35
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 21:51:54

US3032211

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User entered 'I'	System	08 Oct 2020 21:51:54

US3032211

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:47:18
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:56:35
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 21:52:08

US3032211

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:47:18
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Signature has been broken.	(b) (4)	
	Samantha Wieseler (b) (4)	04 Dec 2020 15:31:10
	(b) (4)	
User entered '1 Oct 2020' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	04 Dec 2020 15:31:10
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:56:35
	(b) (4)	
User entered '8 Oct 2020'	Kelsey Kelley (b) (4)	08 Oct 2020 21:52:08
	(b) (4)	

US3032211

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:47:18
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:56:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 21:52:08

US3032211

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:47:18
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:56:35
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 21:52:08

US3032211

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:47:22
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:56:35
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 21:52:15

US3032211

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User entered 'I'	System	08 Oct 2020 21:52:15

US3032211

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:33:27
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 16:17:45

US3032211

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:33:27
User entered '8 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	13 Oct 2020 16:18:03
User entered '13 Oct 2020'	(b) (4)	
	Kelsey Kelley (b) (4)	13 Oct 2020 16:17:45
	(b) (4)	

US3032211

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:33:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 16:17:45

US3032211

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:33:27
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 16:17:45

US3032211

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
DataPoint Verified.		17 Dec 2020 18:48:01
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:33:27
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 16:17:47

US3032211

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User entered 'I'	System	13 Oct 2020 16:17:47

US3032211

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:48:08
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:33:27
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 16:18:43

US3032211

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:48:08
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:33:27
User entered '13 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 16:18:43

US3032211

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:47

[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 19:15:08
DataPoint Verified.		17 Dec 2020 18:48:08
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:33:27
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 16:18:43

US3032211

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
User entered 'VISIT3'	System	13 Oct 2020 16:18:43

US3032211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:48:54
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:33:27
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 16:19:48

US3032211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:48:54
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:33:27
User entered '13 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 16:19:48

US3032211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:48:54
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:33:27
User entered '08:11'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 16:19:48

US3032211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
User entered '13 Oct 2020 08:11'	System	13 Oct 2020 16:19:48

US3032211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:48:54
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:33:27
User entered '36.7' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 16:19:48

US3032211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:48:54
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:33:27
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 16:19:48

US3032211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:48:54
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:33:27
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 16:19:48

US3032211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:48:54
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:33:27
User entered '80'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 16:19:48

US3032211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
User entered 'bpm'	System	13 Oct 2020 16:19:48

US3032211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:48:54
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:33:27
User entered '14'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 16:19:48

US3032211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
User entered 'breaths/min'	System	13 Oct 2020 16:19:48

US3032211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:48:54
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:33:27
User entered '105'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 16:19:48

US3032211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
User entered 'mmHg'	System	13 Oct 2020 16:19:48

US3032211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:48:54
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:33:27
User entered '83'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 16:19:48

US3032211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
User entered 'mmHg'	System	13 Oct 2020 16:19:48

US3032211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08

US3032211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08

US3032211

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:53:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:49:57
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:33:27
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 16:19:55

US3032211

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:53:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:49:57
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:33:27
User entered '13 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 16:19:55

US3032211

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:50:08
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:33:27
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 16:20:15

US3032211

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:50:08
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:33:27
User entered '13 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 16:20:15

US3032211

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:50:08
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:33:27
User entered '08:32'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 16:20:15

US3032211

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
User entered '13 Oct 2020 08:32'	System	13 Oct 2020 16:20:15

US3032211

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
DataPoint Verified.		17 Dec 2020 18:50:12
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:33:27
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 16:20:19

US3032211

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:08
User entered '1'	System	13 Oct 2020 16:20:19

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
Data entry locked.	System	18 Aug 2020 17:41:19
User entered 'Day 64'	System	18 Aug 2020 17:41:19

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

Have you had 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 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-10-20T12:00:27', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '5d814d61-6ae2-4707-9f94-ade3155eaf3a' User entered 'No (N)'	System	20 Oct 2020 17:00:54
	System	20 Oct 2020 17:00:54

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

Have you been exposed to someone with known SARS-CoV-2 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 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-10-20T12:00:38', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '5d814d61-6ae2-4707-9f94-ade3155eaf3a' User entered 'No (N)'	System	20 Oct 2020 17:00:54
	System	20 Oct 2020 17:00:54

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B959A01-B9CB-4F32-9B45-DC3011F02747)', Time: '2020-10-20T12:00:46', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '5d814d61-6ae2-4707-9f94-ade3155eaf3a' User entered '20 Oct 2020 12:00:46'	System	20 Oct 2020 17:00:54
	System	20 Oct 2020 17:00:54

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
Data entry locked.	System	18 Aug 2020 17:41:19
User entered '18 Oct 2020 00:01'	System	18 Aug 2020 17:41:19

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:48
Data entry locked.	System	18 Aug 2020 17:41:19
User entered '22 Oct 2020 23:59'	System	18 Aug 2020 17:41:19

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17
Data entry locked.	System	18 Aug 2020 17:41:19
User entered 'Day 71'	System	18 Aug 2020 17:41:19

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 21:53:47

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 21:53:47

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: 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)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: 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)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

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[Please 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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Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
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US3032211

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17
Data entry locked.	System	18 Aug 2020 17:41:19
User entered '25 Oct 2020 00:01'	System	18 Aug 2020 17:41:19

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17
Data entry locked.	System	18 Aug 2020 17:41:19
User entered '29 Oct 2020 23:59'	System	18 Aug 2020 17:41:19

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17
Data entry locked.	System	18 Aug 2020 17:41:19
User entered 'Day 78'	System	18 Aug 2020 17:41:19

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Have you had 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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Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: 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)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
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[Please contact your study clinic 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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US3032211

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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)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3032211

Folder: Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3032211

Folder: Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
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US3032211

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

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Generated On: 11 Aug 2021 21:53:47

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 21:53:47

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

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Generated On: 11 Aug 2021 21:53:47

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

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Generated On: 11 Aug 2021 21:53:47

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3032211

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Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
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US3032211

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 21:53:47

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

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Generated On: 11 Aug 2021 21:53:47

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 21:53:47

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3032211

Folder: Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: 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)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
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Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
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[Date and time of submission](#)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17
Data entry locked.	System	18 Aug 2020 17:41:19
User entered '01 Nov 2020 00:01'	System	18 Aug 2020 17:41:19

US3032211

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17
Data entry locked.	System	18 Aug 2020 17:41:19
User entered '05 Nov 2020 23:59'	System	18 Aug 2020 17:41:19

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17
Data entry locked.	System	18 Aug 2020 17:41:19
User entered 'Day 92'	System	18 Aug 2020 17:41:19

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
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Folder: 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)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17
Data entry locked.	System	18 Aug 2020 17:41:19
User entered '15 Nov 2020 00:01'	System	18 Aug 2020 17:41:19

US3032211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:16:17
Data entry locked.	System	18 Aug 2020 17:41:19
User entered '19 Nov 2020 23:59'	System	18 Aug 2020 17:41:19

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Have you had 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 (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-01-14T02:10:44', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'e9a3c6cc-153d-4b6f-af06-1e872e408ccb' User entered 'No (N)'	System	14 Jan 2021 08:11:05
	System	14 Jan 2021 08:11:05

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

Have you been exposed to someone with known SARS-CoV-2 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 (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-01-14T02:10:53', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'e9a3c6cc-153d-4b6f-af06-1e872e408ccb' User entered 'No (N)'	System	14 Jan 2021 08:11:05

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-01-14T02:11:00', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'e9a3c6cc-153d-4b6f-af06-1e872e408ccb' User entered '14 Jan 2021 02:11:00'	System	14 Jan 2021 08:11:05
	System	14 Jan 2021 08:11:05

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Have you had 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 (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-01-21T10:25:39', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'a28ebd95-3af0-4018-a69f-5659fe0922bf' User entered 'No (N)'	System	21 Jan 2021 16:25:52
	System	21 Jan 2021 16:25:52

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Have you been exposed to someone with known SARS-CoV-2 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 (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-01-21T10:25:43', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'a28ebd95-3af0-4018-a69f-5659fe0922bf' User entered 'No (N)'	System	21 Jan 2021 16:25:52

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-01-21T10:25:50', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'a28ebd95-3af0-4018-a69f-5659fe0922bf' User entered '21 Jan 2021 10:25:50'	System	21 Jan 2021 16:25:52

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Have you had 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 (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-01-28T01:46:23', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'a82fe030-0d2f-4902-98a3-96e4e6355bab' User entered 'No (N)'	System	28 Jan 2021 07:46:33
	System	28 Jan 2021 07:46:33

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

Have you been exposed to someone with known SARS-CoV-2 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 (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-01-28T01:46:26', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'a82fe030-0d2f-4902-98a3-96e4e6355bab'	System	28 Jan 2021 07:46:33
User entered 'No (N)'	System	28 Jan 2021 07:46:33

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-01-28T01:46:29', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'a82fe030-0d2f-4902-98a3-96e4e6355bab' User entered '28 Jan 2021 01:46:29'	System	28 Jan 2021 07:46:33
	System	28 Jan 2021 07:46:33

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Have you had 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 (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-02-07T16:09:22', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '303a277f-e0e9-4a73-a66b-5544ecf33dd7'	System	07 Feb 2021 22:09:37
User entered 'No (N)'	System	07 Feb 2021 22:09:37

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Have you been exposed to someone with known SARS-CoV-2 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 (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-02-07T16:09:30', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '303a277f-e0e9-4a73-a66b-5544ecf33dd7'	System	07 Feb 2021 22:09:37
User entered 'No (N)'	System	07 Feb 2021 22:09:37

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-02-07T16:09:34', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '303a277f-e0e9-4a73-a66b-5544ecf33dd7' User entered '07 Feb 2021 16:09:34'	System	07 Feb 2021 22:09:37
	System	07 Feb 2021 22:09:37

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Have you had 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 (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-02-11T06:30:36', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '8aac79e0-3943-4690-82ac-d9690ebf1374' User entered 'No (N)'	System	11 Feb 2021 12:30:48
	System	11 Feb 2021 12:30:48

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

Have you been exposed to someone with known SARS-CoV-2 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 (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-02-11T06:30:39', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '8aac79e0-3943-4690-82ac-d9690ebf1374'	System	11 Feb 2021 12:30:48
User entered 'No (N)'	System	11 Feb 2021 12:30:48

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-02-11T06:30:44', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '8aac79e0-3943-4690-82ac-d9690ebf1374' User entered '11 Feb 2021 06:30:44'	System	11 Feb 2021 12:30:48
	System	11 Feb 2021 12:30:48

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Have you had 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 (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-02-21T07:30:39', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '301f67dd-467d-450f-826b-ad68a40c6398' User entered 'No (N)'	System	21 Feb 2021 13:30:53
	System	21 Feb 2021 13:30:53

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

Have you been exposed to someone with known SARS-CoV-2 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 (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-02-21T07:30:45', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '301f67dd-467d-450f-826b-ad68a40c6398' User entered 'No (N)'	System	21 Feb 2021 13:30:53
	System	21 Feb 2021 13:30:53

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-02-21T07:30:50', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '301f67dd-467d-450f-826b-ad68a40c6398' User entered '21 Feb 2021 07:30:50'	System	21 Feb 2021 13:30:53
	System	21 Feb 2021 13:30:53

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Have you had 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 (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-02-28T17:59:56-06:00', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'c7f3c6cf-869f-4874-b8bc-ade631e07798'	System	01 Mar 2021 00:00:15
User entered 'No (N)'	System	01 Mar 2021 00:00:15

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Have you been exposed to someone with known SARS-CoV-2 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 (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-02-28T18:00:02-06:00', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'c7f3c6cf-869f-4874-b8bc-ade631e07798'	System	01 Mar 2021 00:00:15
User entered 'No (N)'	System	01 Mar 2021 00:00:15

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-02-28T18:00:05-06:00', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'c7f3c6cf-869f-4874-b8bc-ade631e07798'	System	01 Mar 2021 00:00:15
User entered '01 Mar 2021 00:00:05'	System	01 Mar 2021 00:00:15

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Have you had 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 (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-03-05T05:21:53-06:00', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '31f29358-daaa-48d5-8b40-49de72d18f91'	System	05 Mar 2021 11:22:04
User entered 'No (N)'	System	05 Mar 2021 11:22:04

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Have you been exposed to someone with known SARS-CoV-2 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 (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-03-05T05:21:57-06:00', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '31f29358-daaa-48d5-8b40-49de72d18f91'	System	05 Mar 2021 11:22:04
User entered 'No (N)'	System	05 Mar 2021 11:22:04

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-03-05T05:22:00-06:00', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '31f29358-daaa-48d5-8b40-49de72d18f91'	System	05 Mar 2021 11:22:04
User entered '05 Mar 2021 05:22:00'	System	05 Mar 2021 11:22:04

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Have you had 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 (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-03-11T00:12:44-06:00', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '49acd6cf-39c0-419c-9b82-fb9f9a1e6132'	System	11 Mar 2021 06:12:54
User entered 'No (N)'	System	11 Mar 2021 06:12:54

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Have you been exposed to someone with known SARS-CoV-2 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 (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-03-11T00:12:47-06:00', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '49acd6cf-39c0-419c-9b82-fb9f9a1e6132'	System	11 Mar 2021 06:12:54
User entered 'No (N)'	System	11 Mar 2021 06:12:54

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-03-11T00:12:50-06:00', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '49acd6cf-39c0-419c-9b82-fb9f9a1e6132'	System	11 Mar 2021 06:12:54
User entered '11 Mar 2021 00:12:50'	System	11 Mar 2021 06:12:54

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Have you had 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 (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-03-18T00:02:15-05:00', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'ed1179b0-9040-4534-8ea0-0015e8f5d5bc'	System	18 Mar 2021 05:02:32
User entered 'No (N)'	System	18 Mar 2021 05:02:32

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

Have you been exposed to someone with known SARS-CoV-2 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 (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-03-18T00:02:19-05:00', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'ed1179b0-9040-4534-8ea0-0015e8f5d5bc'	System	18 Mar 2021 05:02:32
User entered 'No (N)'	System	18 Mar 2021 05:02:32

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-03-18T00:02:22-05:00', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'ed1179b0-9040-4534-8ea0-0015e8f5d5bc' User entered '18 Mar 2021 00:02:22'	System	18 Mar 2021 05:02:32
	System	18 Mar 2021 05:02:32

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Have you had 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 (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-03-25T01:17:17-05:00', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '5d8575a5-ee4c-4cf0-8ece-bfca9a879613'	System	25 Mar 2021 06:17:28
User entered 'No (N)'	System	25 Mar 2021 06:17:28

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

Have you been exposed to someone with known SARS-CoV-2 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 (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-03-25T01:17:21-05:00', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '5d8575a5-ee4c-4cf0-8ece-bfca9a879613'	System	25 Mar 2021 06:17:28
User entered 'No (N)'	System	25 Mar 2021 06:17:28

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-03-25T01:17:25-05:00', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '5d8575a5-ee4c-4cf0-8ece-bfca9a879613'	System	25 Mar 2021 06:17:28
User entered '25 Mar 2021 01:17:25'	System	25 Mar 2021 06:17:28

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Have you had 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 (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-04-01T02:01:04-05:00', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '07c498f4-4caf-4029-b953-d60b9108187a' User entered 'No (N)'	System	01 Apr 2021 07:01:14
	System	01 Apr 2021 07:01:14

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

Have you been exposed to someone with known SARS-CoV-2 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 (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-04-01T02:01:08-05:00', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '07c498f4-4caf-4029-b953-d60b9108187a' User entered 'No (N)'	System	01 Apr 2021 07:01:14
	System	01 Apr 2021 07:01:14

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-04-01T02:01:11-05:00', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '07c498f4-4caf-4029-b953-d60b9108187a' User entered '01 Apr 2021 02:01:11'	System	01 Apr 2021 07:01:14
	System	01 Apr 2021 07:01:14

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Have you had 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 (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-04-08T06:21:09-05:00', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '2b5b17d3-3ba5-4612-98c4-1a7fb42ad390'	System	08 Apr 2021 11:21:22
User entered 'No (N)'	System	08 Apr 2021 11:21:22

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Have you been exposed to someone with known SARS-CoV-2 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 (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-04-08T06:21:12-05:00', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '2b5b17d3-3ba5-4612-98c4-1a7fb42ad390'	System	08 Apr 2021 11:21:22
User entered 'No (N)'	System	08 Apr 2021 11:21:22

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-04-08T06:21:15-05:00', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '2b5b17d3-3ba5-4612-98c4-1a7fb42ad390'	System	08 Apr 2021 11:21:22
User entered '08 Apr 2021 06:21:15'	System	08 Apr 2021 11:21:22

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Have you had 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 (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-04-15T10:22:08-05:00', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '6f4c19f1-eb79-4045-876f-177e2202b6dd'	System	15 Apr 2021 15:22:17
User entered 'No (N)'	System	15 Apr 2021 15:22:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Have you been exposed to someone with known SARS-CoV-2 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 (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-04-15T10:22:11-05:00', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '6f4c19f1-eb79-4045-876f-177e2202b6dd'	System	15 Apr 2021 15:22:17
User entered 'No (N)'	System	15 Apr 2021 15:22:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-04-15T10:22:15-05:00', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '6f4c19f1-eb79-4045-876f-177e2202b6dd' User entered '15 Apr 2021 10:22:15'	System	15 Apr 2021 15:22:17
	System	15 Apr 2021 15:22:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Have you had 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 (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-04-22T00:02:53-05:00', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'e0ef77ad-6d2c-4e10-92da-8f770b028d9f' User entered 'No (N)'	System	22 Apr 2021 05:03:03
	System	22 Apr 2021 05:03:03

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Have you been exposed to someone with known SARS-CoV-2 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 (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-04-22T00:02:57-05:00', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'e0ef77ad-6d2c-4e10-92da-8f770b028d9f'	System	22 Apr 2021 05:03:03
User entered 'No (N)'	System	22 Apr 2021 05:03:03

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-04-22T00:02:59-05:00', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'e0ef77ad-6d2c-4e10-92da-8f770b028d9f'	System	22 Apr 2021 05:03:03
User entered '22 Apr 2021 00:02:59'	System	22 Apr 2021 05:03:03

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Have you had 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 (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-04-29T02:33:48-05:00', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '2f66bf9a-1992-400e-947b-2928172b138d' User entered 'No (N)'	System	29 Apr 2021 07:34:03
	System	29 Apr 2021 07:34:03

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

Have you been exposed to someone with known SARS-CoV-2 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 (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-04-29T02:33:50-05:00', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '2f66bf9a-1992-400e-947b-2928172b138d' User entered 'No (N)'	System	29 Apr 2021 07:34:03
	System	29 Apr 2021 07:34:03

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-04-29T02:33:54-05:00', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: '2f66bf9a-1992-400e-947b-2928172b138d' User entered '29 Apr 2021 02:33:54'	System	29 Apr 2021 07:34:03
	System	29 Apr 2021 07:34:03

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 22:16:17

US3032211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:16:17
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 22:16:17

US3032211

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 21:53:47

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-02-28T17:59:44-06:00', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'a0e013a2-1940-47a6-8f91-8b559dce91cc' User entered 'No (N)'	System	28 Feb 2021 23:59:51
	System	28 Feb 2021 23:59:51

US3032211

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 21:53:47

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F055780C-92AD-4843-9F8B-D5125E1B37BB)', Time: '2021-02-28T17:59:48-06:00', User OID: 'PatientReportedOutcome (US3032211)', ODM File OID: 'a0e013a2-1940-47a6-8f91-8b559dce91cc' User entered '28 Feb 2021 23:59:48'	System	28 Feb 2021 23:59:51
	System	28 Feb 2021 23:59:51

US3032211

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:37:38
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	09 Mar 2021 22:17:49

US3032211

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:37:38
User entered '09 Nov 2020'	(b) (4) Samantha Wieseler (b) (4)	09 Mar 2021 22:17:49

US3032211

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:37:38
User entered 'Contact Made (CONTACT MADE)'	Samantha Wieseler (b) (4)	09 Mar 2021 22:17:49

US3032211

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:37:38
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	09 Mar 2021 22:17:49

US3032211

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:37:38
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	09 Mar 2021 22:17:53

US3032211

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:15:06
User entered 'I'	System	09 Mar 2021 22:17:53

US3032211

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:37:38
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	09 Mar 2021 22:21:00

US3032211

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:37:38
User entered '13 Dec 2020'	Samantha Wieseler (b) (4)	09 Mar 2021 22:21:00

US3032211

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:37:38
User entered 'Contact Made (CONTACT MADE)'	Samantha Wieseler (b) (4)	09 Mar 2021 22:21:00

US3032211

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:37:38
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	09 Mar 2021 22:21:00

US3032211

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:37:38
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	09 Mar 2021 22:21:06

US3032211

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User entered 'I'	System	09 Mar 2021 22:21:06

US3032211

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:37:38
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	09 Mar 2021 22:23:16

US3032211

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:37:38
User entered '12 Jan 2021'	Samantha Wieseler (b) (4)	09 Mar 2021 22:23:16

US3032211

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:37:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wieseler (b) (4)	09 Mar 2021 22:23:16

US3032211

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:37:38
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	09 Mar 2021 22:23:16

US3032211

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:37:38
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	09 Mar 2021 22:23:19

US3032211

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User entered 'I'	System	09 Mar 2021 22:23:19

US3032211

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:37:38
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	09 Mar 2021 22:25:21

US3032211

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:37:38
User entered '11 Feb 2021'	Samantha Wieseler (b) (4)	09 Mar 2021 22:25:21

US3032211

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:37:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wieseler (b) (4)	09 Mar 2021 22:25:21

US3032211

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:37:38
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	09 Mar 2021 22:25:21

US3032211

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:37:38
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	09 Mar 2021 22:25:25

US3032211

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User entered 'I'	System	09 Mar 2021 22:25:25

US3032211

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:16:19
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	15 Mar 2021 17:29:52

US3032211

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:16:19
User entered '15 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	15 Mar 2021 17:29:52
	(b) (4)	

US3032211

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:47

[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 14:01:54
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:16:19
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Mar 2021 17:29:52

US3032211

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User entered 'VISIT4'	System	15 Mar 2021 17:29:52

US3032211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:39:10
User entered 'No (N)'	(b) (4) Samantha Wieseler (b) (4)	30 Mar 2021 21:28:59

US3032211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:39:10
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	30 Mar 2021 21:28:59

US3032211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:39:10
User entered empty.	Samantha Wieseler (b) (4)	30 Mar 2021 21:28:59

US3032211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User entered empty.	System	30 Mar 2021 21:28:59

US3032211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:39:10
User entered empty.	Samantha Wieseler (b) (4)	30 Mar 2021 21:28:59

US3032211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:39:10
User entered empty.	Samantha Wieseler (b) (4)	30 Mar 2021 21:28:59

US3032211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:39:10
User entered empty.	Samantha Wieseler (b) (4)	30 Mar 2021 21:28:59

US3032211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:39:10
User entered empty.	Samantha Wieseler (b) (4)	30 Mar 2021 21:28:59

US3032211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User entered empty.	System	30 Mar 2021 21:28:59

US3032211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:39:10
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	30 Mar 2021 21:28:59

US3032211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User entered empty.	System	30 Mar 2021 21:28:59

US3032211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:39:10
User entered empty.	Samantha Wieseler (b) (4)	30 Mar 2021 21:28:59

US3032211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User entered empty.	System	30 Mar 2021 21:28:59

US3032211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:39:10
User entered empty.	Samantha Wieseler (b) (4)	30 Mar 2021 21:28:59

US3032211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User entered empty.	System	30 Mar 2021 21:28:59

US3032211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54

US3032211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:47

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54

US3032211

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:53:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:16:19
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	15 Mar 2021 17:30:00

US3032211

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:53:47

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:16:19
User entered empty.	Kelsey Kelley (b) (4)	15 Mar 2021 17:30:00

US3032211

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:16:19
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	15 Mar 2021 17:30:09

US3032211

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:16:19
User entered '15 Mar 2021'	Kelsey Kelley (b) (4)	15 Mar 2021 17:30:09

US3032211

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:16:19
User entered '09:30'	Kelsey Kelley (b) (4)	15 Mar 2021 17:30:09

US3032211

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User entered '15 Mar 2021 09:30'	System	15 Mar 2021 17:30:09

US3032211

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:16:19
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	15 Mar 2021 17:30:13

US3032211

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:01:54
User entered 'I'	System	15 Mar 2021 17:30:13

US3032211

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:28:41

US3032211

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:50
User entered '14 Apr 2021'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:28:41

US3032211

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:28:41

US3032211

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:50
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:28:41

US3032211

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:28:47

US3032211

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 20:28:47

US3032211

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:53:47

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:40
DataPoint Verified.		10 Mar 2021 19:35:50
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:49
User entered '10 Sep 2020'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 15:45:46

US3032211

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:53:47

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:40
DataPoint Verified.		10 Mar 2021 19:35:50
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:49
User entered '10:50'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 15:45:46

US3032211

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:53:47

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:40
User entered '10 Sep 2020 10:50'	System	23 Nov 2020 15:45:46

US3032211

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:53:47

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:40
DataPoint Verified.		10 Mar 2021 19:35:50
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:49
User entered 'Safety Call (Safety Call)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 15:45:46

US3032211

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:53:47

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:40
DataPoint Verified.		10 Mar 2021 19:35:50
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:49
User entered 'No (N)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 15:45:46

US3032211

Folder: Covid-19 Assessment 10 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 21:53:47

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:40
DataPoint Verified.		10 Mar 2021 19:35:54
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:49
User entered 'No (N)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 15:45:51

US3032211

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

Form: Visit Date

Generated On: 11 Aug 2021 21:53:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	09 Jan 2021 20:02:53

US3032211

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

Form: Visit Date

Generated On: 11 Aug 2021 21:53:47

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:02
User closed query 'Per CDM, re-query: Response noted. The visit date should equal the date of earliest assessment completed. Please update the visit date accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:45:41
User entered '13 Jan 2021' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	29 Jan 2021 14:25:08
Query 'Per CDM, re-query: Response noted. The visit date should equal the date of earliest assessment completed. Please update the visit date accordingly. ' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	28 Jan 2021 15:26:52
Signature has been broken.	Samantha Wieseler (b) (4) (b) (4)	28 Jan 2021 15:26:44
User entered '09 Jan 2021' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	28 Jan 2021 15:26:44
User opened query 'Per CDM, re-query: Response noted. The visit date should equal the date of earliest assessment completed. Please update the visit date accordingly. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 11:25:21
User closed query 'Per CDM: Please note that there is data recorded for 09 Jan 2021 within this folder which is before the visit date. Per CCGs, dates should be chronological. The visit date should equal the date of earliest assessment completed. Kindly review and update as appropriate. ' (Site from DM).		25 Jan 2021 08:59:44
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:29:45
Query 'Per CDM: Please note that there is data recorded for 09 Jan 2021 within this folder which is before the visit date. Per CCGs, dates should be chronological. The visit date should equal the date of earliest assessment completed. Kindly review and update as appropriate. ' answered with 'will update accordingly' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	15 Jan 2021 01:12:01

US3032211

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

Form: Visit Date

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
User opened query 'Per CDM: Please note that there is data recorded for 09 Jan 2021 within this folder which is before the visit date. Per CCGs, dates should be chronological. The visit date should equal the date of earliest assessment completed. Kindly review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 14:37:37
User entered '13 Jan 2021' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	13 Jan 2021 22:50:19
User entered '9 Jan 2021'	Kelsey Kelley (b) (4)	09 Jan 2021 20:02:53

US3032211

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

Form: Visit Date

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered 'Clinic (Clinic)'	Kelsey Kelley (b) (4)	09 Jan 2021 20:02:53

US3032211

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

Form: Visit Date

Generated On: 11 Aug 2021 21:53:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered 'UNBLND_DECIDE'	System	09 Jan 2021 20:02:53

US3032211

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

Form: Unblinding

Generated On: 11 Aug 2021 21:53:47

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered '9 Jan 2021'	Kelsey Kelley (b) (4)	09 Jan 2021 20:04:09

US3032211

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

Form: Unblinding

Generated On: 11 Aug 2021 21:53:47

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:37:38
User entered '0'	Samantha Wieseler (b) (4)	09 Mar 2021 22:25:33
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:00:21

US3032211

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

Form: Unblinding

Generated On: 11 Aug 2021 21:53:47

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	09 Jan 2021 20:04:09

US3032211

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

Form: Unblinding

Generated On: 11 Aug 2021 21:53:47

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:37:38
User entered 'Amendment 6 or later (Amendment 6 or later)'	Samantha Wieseler (b) (4)	09 Mar 2021 22:25:33
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:00:21

US3032211

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

Form: Unblinding

Generated On: 11 Aug 2021 21:53:47

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered '9 Jan 2021'	Kelsey Kelley (b) (4)	09 Jan 2021 20:04:09

US3032211

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

Form: Unblinding

Generated On: 11 Aug 2021 21:53:47

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered 'Placebo (Placebo)'	(b) (4) Kelsey Kelley (b) (4)	09 Jan 2021 20:04:09

US3032211

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

Form: Unblinding

Generated On: 11 Aug 2021 21:53:47

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 07:37:07
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered 'Placebo (Placebo)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Jan 2021 20:04:09

US3032211

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

Form: Unblinding

Generated On: 11 Aug 2021 21:53:47

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 07:37:07
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered 'Placebo (Placebo)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Jan 2021 20:04:09

US3032211

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

Form: Unblinding

Generated On: 11 Aug 2021 21:53:47

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	09 Jan 2021 20:04:09

US3032211

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

Form: Unblinding

Generated On: 11 Aug 2021 21:53:47

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered '1'	System	09 Jan 2021 20:04:09

US3032211

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

Form: Unblinding

Generated On: 11 Aug 2021 21:53:47

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered 'I'	System	09 Jan 2021 20:04:09

US3032211

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:53:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4)	09 Jan 2021 20:06:28

US3032211

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:53:47

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4)	09 Jan 2021 20:06:28

US3032211

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:53:47

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered empty.	System	09 Jan 2021 20:06:28
DataPoint set to visible.	System	09 Jan 2021 20:04:09

US3032211

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:53:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4)	09 Jan 2021 20:06:28

US3032211

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:53:47

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4)	09 Jan 2021 20:06:28

US3032211

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:53:47

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered empty.	System	09 Jan 2021 20:06:28
DataPoint set to visible.	System	09 Jan 2021 20:04:09

US3032211

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	09 Jan 2021 20:06:28

US3032211

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	13 Jan 2021 22:51:31
User entered 'No (N)'	(b) (4)	
	Kelsey Kelley (b) (4)	09 Jan 2021 20:06:28
	(b) (4)	

US3032211

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	29 Jan 2021 14:25:08
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	28 Jan 2021 15:26:44
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered '13 Jan 2021' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	13 Jan 2021 22:51:31
User entered empty.	Kelsey Kelley (b) (4)	09 Jan 2021 20:06:28

US3032211

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered '14:51' reason for change: Data Entry Error	(b) (4)	13 Jan 2021 22:51:31
User entered empty.	Kelsey Kelley (b) (4)	09 Jan 2021 20:06:28
	(b) (4)	

US3032211

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered '13 Jan 2021 14:51'	System	13 Jan 2021 22:51:31
User entered empty.	System	09 Jan 2021 20:06:28

US3032211

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered '36.4' C reason for change: Data Entry Error	(b) (4)	13 Jan 2021 22:51:31
User entered empty.	Kelsey Kelley (b) (4)	09 Jan 2021 20:06:28
	(b) (4)	

US3032211

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	13 Jan 2021 22:51:31
User entered empty.	Kelsey Kelley (b) (4)	09 Jan 2021 20:06:28
	(b) (4)	

US3032211

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	09 Jan 2021 20:06:28

US3032211

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered '71' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	13 Jan 2021 22:51:31
User entered empty.	(b) (4)	
	Kelsey Kelley (b) (4)	09 Jan 2021 20:06:28
	(b) (4)	

US3032211

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered 'bpm'	System	13 Jan 2021 22:51:31
User entered empty.	System	09 Jan 2021 20:06:28

US3032211

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered '15' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	13 Jan 2021 22:51:31
User entered empty.	(b) (4)	
	Kelsey Kelley (b) (4)	09 Jan 2021 20:06:28
	(b) (4)	

US3032211

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered 'breaths/min'	System	13 Jan 2021 22:51:31
User entered empty.	System	09 Jan 2021 20:06:28

US3032211

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered '111' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	13 Jan 2021 22:51:31
User entered empty.	(b) (4)	
	Kelsey Kelley (b) (4)	09 Jan 2021 20:06:28
	(b) (4)	

US3032211

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered 'mmHg'	System	13 Jan 2021 22:51:31
User entered empty.	System	09 Jan 2021 20:06:28

US3032211

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered '76' reason for change: Data Entry Error	(b) (4) Kelsey Kelley (b) (4)	13 Jan 2021 22:51:31
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	09 Jan 2021 20:06:28

US3032211

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered 'mmHg'	System	13 Jan 2021 22:51:31
User entered empty.	System	09 Jan 2021 20:06:28

US3032211

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:53:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4)	09 Jan 2021 20:06:28

US3032211

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:53:47

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4)	09 Jan 2021 20:06:28

US3032211

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:53:47

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered empty.	System	09 Jan 2021 20:06:28
DataPoint set to visible.	System	09 Jan 2021 20:04:09

US3032211

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	09 Jan 2021 20:06:28

US3032211

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	13 Jan 2021 22:54:08
User entered 'No (N)'	(b) (4)	
	Kelsey Kelley (b) (4)	09 Jan 2021 20:06:28
	(b) (4)	

US3032211

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	29 Jan 2021 14:25:08
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	28 Jan 2021 15:26:44
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered '13 Jan 2021' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	13 Jan 2021 22:54:08
User entered empty.	Kelsey Kelley (b) (4)	09 Jan 2021 20:06:28

US3032211

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered '15:57' reason for change: Data Entry Error	(b) (4)	13 Jan 2021 22:54:08
User entered empty.	Kelsey Kelley (b) (4)	09 Jan 2021 20:06:28
	(b) (4)	

US3032211

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered '13 Jan 2021 15:57'	System	13 Jan 2021 22:54:08
User entered empty.	System	09 Jan 2021 20:06:28

US3032211

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered '36.7' C reason for change: Data Entry Error	(b) (4)	13 Jan 2021 22:54:08
User entered empty.	Kelsey Kelley (b) (4)	09 Jan 2021 20:06:28
	(b) (4)	

US3032211

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	13 Jan 2021 22:54:08
User entered empty.	Kelsey Kelley (b) (4)	09 Jan 2021 20:06:28
	(b) (4)	

US3032211

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	09 Jan 2021 20:06:28

US3032211

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered '65' reason for change: Data Entry Error	(b) (4)	13 Jan 2021 22:54:08
User entered empty.	Kelsey Kelley (b) (4)	09 Jan 2021 20:06:28
	(b) (4)	

US3032211

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered 'bpm'	System	13 Jan 2021 22:54:08
User entered empty.	System	09 Jan 2021 20:06:28

US3032211

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered '14' reason for change: Data Entry Error	(b) (4)	13 Jan 2021 22:54:08
User entered empty.	Kelsey Kelley (b) (4)	09 Jan 2021 20:06:28
	(b) (4)	

US3032211

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered 'breaths/min'	System	13 Jan 2021 22:54:08
User entered empty.	System	09 Jan 2021 20:06:28

US3032211

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered '104' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	13 Jan 2021 22:54:08
User entered empty.	(b) (4)	
	Kelsey Kelley (b) (4)	09 Jan 2021 20:06:28
	(b) (4)	

US3032211

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered 'mmHg'	System	13 Jan 2021 22:54:08
User entered empty.	System	09 Jan 2021 20:06:28

US3032211

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered '75' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	13 Jan 2021 22:54:08
User entered empty.	Kelsey Kelley (b) (4)	09 Jan 2021 20:06:28

US3032211

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered 'mmHg'	System	13 Jan 2021 22:54:08
User entered empty.	System	09 Jan 2021 20:06:28

US3032211

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

Form: Physical Examination

Generated On: 11 Aug 2021 21:53:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	09 Jan 2021 20:04:53

US3032211

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

Form: Physical Examination

Generated On: 11 Aug 2021 21:53:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	29 Jan 2021 14:25:08
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	28 Jan 2021 15:26:44
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	13 Jan 2021 22:51:43
User entered '13 Jan 2021' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	13 Jan 2021 22:51:43
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	13 Jan 2021 22:50:19
User entered '9 Jan 2021'	Kelsey Kelley (b) (4)	09 Jan 2021 20:04:53

US3032211

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User closed query 'Per CDM: Childbearing potential noted as "yes" yet pregnancy test not performed. Kindly review and update as appropriate, else clarify or confirm a pregnancy test will be performed before the subject is dosed.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 12:07:22
Query 'Per CDM: Childbearing potential noted as "yes" yet pregnancy test not performed. Kindly review and update as appropriate, else clarify or confirm a pregnancy test will be performed before the subject is dosed.' answered with 'data updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	13 Jan 2021 22:50:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	13 Jan 2021 22:50:11
User opened query 'Per CDM: Childbearing potential noted as "yes" yet pregnancy test not performed. Kindly review and update as appropriate, else clarify or confirm a pregnancy test will be performed before the subject is dosed.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 09:34:12
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	09 Jan 2021 20:06:14

US3032211

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User closed query 'Date of Test is not equal to Visit Date. Please review and reconcile.' (Site from System).		01 Feb 2021 10:00:24
Query 'Date of Test is not equal to Visit Date. Please review and reconcile.' answered with 'subject was unblinded on the 9th and was delayed for vaccination until the 13th' (Site from System).	Samantha Wieseler (b) (4)	28 Jan 2021 15:28:19
User opened query 'Date of Test is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	
User opened query 'Date of Test is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	28 Jan 2021 15:26:44
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User closed query 'Date of Test is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	
Query 'Date of Test is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	13 Jan 2021 22:50:19
User opened query 'Date of Test is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	13 Jan 2021 22:50:19
User entered '13 Jan 2021' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	13 Jan 2021 22:50:11
User entered empty.	(b) (4)	
	Kelsey Kelley (b) (4)	09 Jan 2021 20:06:14
	(b) (4)	

US3032211

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered 'Urine (URINE)' reason for change:	(b) (4)	
Data Entry Error	Kelsey Kelley (b) (4)	13 Jan 2021 22:50:11
User entered empty.	(b) (4)	
	Kelsey Kelley (b) (4)	09 Jan 2021 20:06:14
	(b) (4)	

US3032211

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered 'Negative (NEGATIVE)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	13 Jan 2021 22:50:11
User entered empty.	Kelsey Kelley (b) (4)	09 Jan 2021 20:06:14

US3032211

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	13 Jan 2021 22:50:11
User entered empty.	Kelsey Kelley (b) (4)	09 Jan 2021 20:06:14
	(b) (4)	

US3032211

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	09 Jan 2021 20:06:14

US3032211

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	09 Jan 2021 20:06:14

US3032211

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered empty.	System	09 Jan 2021 20:06:14

US3032211

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

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	13 Jan 2021 22:52:07
User entered 'No (N)'	(b) (4)	
	Kelsey Kelley (b) (4)	09 Jan 2021 20:05:47
	(b) (4)	

US3032211

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

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered empty; reason for change Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	13 Jan 2021 22:52:07
User entered 'Other (OTHER)'	(b) (4)	
	Kelsey Kelley (b) (4)	09 Jan 2021 20:05:47
	(b) (4)	

US3032211

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

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered empty; reason for change Data Entry Error	Kelsey Kelley (b) (4)	13 Jan 2021 22:52:07
User entered 'Subject will have vaccine delayed due to recently donating blood.'	Kelsey Kelley (b) (4)	09 Jan 2021 20:05:47

US3032211

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

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered 'mRNA-1273'	System	13 Jan 2021 22:52:07
User entered empty.	System	09 Jan 2021 20:05:47
DataPoint set to visible.	System	09 Jan 2021 20:04:09

US3032211

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

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).		01 Feb 2021 09:59:59
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered with 'subject was unblinded on the 9th and was delayed for vaccination until the 13th' (Site from System).	Samantha Wieseler (b) (4)	28 Jan 2021 15:27:40
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	28 Jan 2021 15:26:44
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered '13 Jan 2021' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	13 Jan 2021 22:52:07
User entered empty.	Kelsey Kelley (b) (4)	09 Jan 2021 20:05:47

US3032211

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

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered '15:25' reason for change: Data Entry Error	(b) (4)	13 Jan 2021 22:52:07
User entered empty.	Kelsey Kelley (b) (4)	09 Jan 2021 20:05:47
	(b) (4)	

US3032211

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

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered '13 Jan 2021 15:25'	System	13 Jan 2021 22:52:07
User entered empty.	System	09 Jan 2021 20:05:47

US3032211

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

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	13 Jan 2021 22:52:07
User entered empty.	Kelsey Kelley (b) (4)	09 Jan 2021 20:05:47

US3032211

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

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered 'ONCE'	System	13 Jan 2021 22:52:07
User entered empty.	System	09 Jan 2021 20:05:47

US3032211

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

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered 'INTRAMUSCULAR'	System	13 Jan 2021 22:52:07
User entered empty.	System	09 Jan 2021 20:05:47

US3032211

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	09 Jan 2021 20:04:28

US3032211

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User closed query 'Per GCL Lab Recon: OL Immuno: Response still ambiguous, please kindly confirm in the response with the correct sample collection date, and if applicable send a DCF to PPD GCL, to update the correct sample collection date. Thank you.' (Site from DM).		07 Apr 2021 02:56:48
Query 'Per GCL Lab Recon: OL Immuno: Response still ambiguous, please kindly confirm in the response with the correct sample collection date, and if applicable send a DCF to PPD GCL, to update the correct sample collection date. Thank you.' answered with 'correct draw date is 09Jan2021' (Site from DM).	Samantha Wieseler (b) (4)	31 Mar 2021 13:01:10
User opened query 'Per GCL Lab Recon: OL Immuno: Response still ambiguous, please kindly confirm in the response with the correct sample collection date, and if applicable send a DCF to PPD GCL, to update the correct sample collection date. Thank you.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 10:38:34
User closed query 'Per GCL Lab Recon:OL Immuno It appears there is a collection date mismatch between EDC & PPD GCL for this "OL-D1" sample, as in PPD GCL, it is recorded as collected on "09 JAN 2021", however here in EDC, it is recorded as collected on "13 JAN 2021". Please confirm the correct sample collection date in the response, and then please update the correct sample collection date in EDC or Preclarus as necessary by sending a DCF. Thank you. ' (Site from DM).		31 Mar 2021 10:38:34
Query 'Per GCL Lab Recon:OL Immuno: It appears there is a collection date mismatch between EDC & PPD GCL for this "OL-D1" sample, as in PPD GCL, it is recorded as collected on "09 JAN 2021", however here in EDC, it is recorded as collected on "13 JAN 2021". Please confirm the correct sample collection date in the response, and then please update the correct sample collection date in EDC or Preclarus as necessary by sending a DCF. Thank you. ' answered with 'subject was drawn on 09Jan2021 and delayed rest of visit to 13Jan2021.' (Site from DM).	Linden DeBoer (b) (4)	22 Mar 2021 21:44:27

PRODUCTION RELEASE (v12.003
EAB) (1725)

1485 of 1790

US3032211

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Recon:OL Immuno: It appears there is a collection date mismatch between EDC & PPD GCL for this "OL-D1" sample, as in PPD GCL, it is recorded as collected on "09 JAN 2021", however here in EDC, it is recorded as collected on "13 JAN 2021". Please confirm the correct sample collection date in the response, and then please update the correct sample collection date in EDC or Preclarus as necessary by sending a DCF. Thank you. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	20 Mar 2021 10:17:45
User closed query 'The Collection Date is prior to the Participant Decision Visit Date. Please review and reconcile.' (Site from System). Signature has been broken.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:41
User entered '13 Jan 2021' reason for change: Data Entry Error	(b) (4)	17 Feb 2021 19:35:48
Amendment Manager: User opened query 'The Collection Date is prior to the Participant Decision Visit Date. Please review and reconcile.' (Site from System). User signature succeeded.	Samantha Wieseler (b) (4)	17 Feb 2021 19:35:48
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System). Query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' answered with 'Subject had vaccine delayed due to recently donating blood, immunogenicity was taken on first visit ' (Site from System). User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System). User entered '9 Jan 2021'	Samantha Wieseler (b) (4)	17 Feb 2021 19:35:48
	System	17 Feb 2021 01:10:58
	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
	(b) (4)	14 Jan 2021 14:37:43
	(b) (4), (b) (6)	13 Jan 2021 22:53:28
	Kelsey Kelley (b) (4)	13 Jan 2021 22:50:19
	(b) (4)	09 Jan 2021 20:04:28

US3032211

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered '12:43'	Kelsey Kelley (b) (4)	09 Jan 2021 20:04:28

US3032211

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered '13 Jan 2021 12:43'	System	17 Feb 2021 19:35:48
User entered '9 Jan 2021 12:43'	System	09 Jan 2021 20:04:28

US3032211

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:53:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	09 Jan 2021 20:04:37

US3032211

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:53:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered '9 Jan 2021'	Kelsey Kelley (b) (4)	09 Jan 2021 20:04:37

US3032211

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered '12:47'	(b) (4) Kelsey Kelley (b) (4)	09 Jan 2021 20:04:37

US3032211

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered '9 Jan 2021 12:47'	System	09 Jan 2021 20:04:37

US3032211

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

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	09 Jan 2021 20:04:43

US3032211

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

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:17:48
User entered 'I'	System	09 Jan 2021 20:04:43

US3032211

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:29
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered 'Yes (Y)'	(b) (4) Chelsie Nutsch (b) (4)	09 Feb 2021 20:05:21

US3032211

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:29
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered '20 Jan 2021'	Chelsie Nutsch (b) (4)	09 Feb 2021 20:05:21

US3032211

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:29
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered 'Contact Made (CONTACT MADE)'	Chelsie Nutsch (b) (4)	09 Feb 2021 20:05:21

US3032211

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:29
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered empty.	(b) (4) Chelsie Nutsch (b) (4)	09 Feb 2021 20:05:21

US3032211

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:29
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 19:43:23

US3032211

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:29
User entered 'I'	System	09 Feb 2021 19:43:23

US3032211

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:29
User entered 'I'	System	09 Feb 2021 19:43:23
DataPoint set to visible.	System	09 Feb 2021 19:43:23

US3032211

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 19:47:06

US3032211

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered '9 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 19:47:06
	(b) (4)	

US3032211

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:47

[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 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 19:47:06

US3032211

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User entered 'OLD29'	System	09 Feb 2021 19:47:06

US3032211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 19:50:17

US3032211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 19:50:17

US3032211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered '9 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 19:50:17

US3032211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered '11:36'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 19:50:17

US3032211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User entered '9 Feb 2021 11:36'	System	09 Feb 2021 19:50:17

US3032211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered '37.6' C	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 19:50:17

US3032211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 19:50:17
	(b) (4)	

US3032211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 19:50:17

US3032211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered '71'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 19:50:17

US3032211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User entered 'bpm'	System	09 Feb 2021 19:50:17

US3032211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered '16'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 19:50:17

US3032211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User entered 'breaths/min'	System	09 Feb 2021 19:50:17

US3032211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered '113'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 19:50:17

US3032211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User entered 'mmHg'	System	09 Feb 2021 19:50:17

US3032211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered '84'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 19:50:17

US3032211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User entered 'mmHg'	System	09 Feb 2021 19:50:17

US3032211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 19:51:00

US3032211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 19:51:00

US3032211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered '9 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 19:51:00
	(b) (4)	

US3032211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered '12:45'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 19:51:00

US3032211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User entered '9 Feb 2021 12:45'	System	09 Feb 2021 19:51:00

US3032211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered '36.7' C	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 19:51:00
	(b) (4)	

US3032211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 19:51:00
	(b) (4)	

US3032211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 19:51:00

US3032211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered '70'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 19:51:00

US3032211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User entered 'bpm'	System	09 Feb 2021 19:51:00

US3032211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered '14'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 19:51:00

US3032211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User entered 'breaths/min'	System	09 Feb 2021 19:51:00

US3032211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered '108'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 19:51:00

US3032211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User entered 'mmHg'	System	09 Feb 2021 19:51:00

US3032211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered '87'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 19:51:00

US3032211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User entered 'mmHg'	System	09 Feb 2021 19:51:00

US3032211

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:53:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 19:47:49

US3032211

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:53:47

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered '9 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 19:47:49

US3032211

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 19:48:03

US3032211

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered '9 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 19:48:03

US3032211

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered 'Urine (URINE)'	Kelsey Kelley (b) (4)	09 Feb 2021 19:48:03

US3032211

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered 'Negative (NEGATIVE)'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 19:48:03

US3032211

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 19:48:03

US3032211

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered empty.	Kelsey Kelley (b) (4)	09 Feb 2021 19:48:03

US3032211

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 19:48:03

US3032211

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User entered empty.	System	09 Feb 2021 19:48:03

US3032211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 19:49:09

US3032211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 19:49:09
	(b) (4)	

US3032211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

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 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 19:49:09
	(b) (4)	

US3032211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User entered 'mRNA-1273'	System	09 Feb 2021 19:49:09
DataPoint set to visible.	System	09 Feb 2021 19:43:23

US3032211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered '9 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 19:49:09
	(b) (4)	

US3032211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered '12:10'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 19:49:09

US3032211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User entered '9 Feb 2021 12:10'	System	09 Feb 2021 19:49:09

US3032211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered 'Left Arm (LEFT ARM)'	Kelsey Kelley (b) (4)	09 Feb 2021 19:49:09

US3032211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User entered 'ONCE'	System	09 Feb 2021 19:49:09

US3032211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:47

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User entered 'INTRAMUSCULAR'	System	09 Feb 2021 19:49:09

US3032211

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:06
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 19:49:39

US3032211

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:28
User entered 'I'	System	09 Feb 2021 19:49:39

US3032211

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:29
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:37:38
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	09 Mar 2021 22:28:24

US3032211

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:29
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:37:38
User entered '16 Feb 2021'	Samantha Wieseler (b) (4)	09 Mar 2021 22:28:24

US3032211

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:29
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:37:38
User entered 'Contact Made (CONTACT MADE)'	Samantha Wieseler (b) (4)	09 Mar 2021 22:28:24

US3032211

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:29
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:37:38
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	09 Mar 2021 22:28:24

US3032211

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:29
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:37:38
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	09 Mar 2021 22:28:28

US3032211

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:29
User entered 'I'	System	09 Mar 2021 22:28:28

US3032211

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:16:19
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 17:29:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Mar 2021 17:29:37
User entered 'No (N)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	15 Mar 2021 17:29:37
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 17:29:33
User entered empty; reason for change Data Entry Error	Kelsey Kelley (b) (4)	15 Mar 2021 17:29:33
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	15 Mar 2021 17:27:57
	(b) (4)	

US3032211

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:16:19
	(b) (4)	
User entered empty; reason for change Data Entry Error	Kelsey Kelley (b) (4)	15 Mar 2021 17:29:33
	(b) (4)	
User entered '15 Mar 2021'	Kelsey Kelley (b) (4)	15 Mar 2021 17:27:57
	(b) (4)	

US3032211

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:16:19
	(b) (4)	
User entered empty; reason for change Data Entry Error	Kelsey Kelley (b) (4)	15 Mar 2021 17:29:33
	(b) (4)	
User entered 'Clinic (Clinic)'	Kelsey Kelley (b) (4)	15 Mar 2021 17:27:57
	(b) (4)	

US3032211

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:47

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	15 Mar 2021 17:29:37
User entered empty.	System	15 Mar 2021 17:29:33
User entered 'OLD57'	System	15 Mar 2021 17:27:57

US3032211

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 21:53:47

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:54:35
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:25
User closed query 'Per CDM: "Did participant experience any adverse event" recorded "No" however adverse events recorded corresponding page. Please review and update accordingly. else clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Dec 2020 04:04:49
Query 'Per CDM: "Did participant experience any adverse event" recorded "No" however adverse event recorded corresponding page. Please review and update accordingly. else clarify' answered with 'data corrected' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	23 Dec 2020 20:06:52
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	23 Dec 2020 20:06:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	23 Dec 2020 20:06:39
User opened query 'Per CDM: "Did participant experience any adverse event" recorded "No" however adverse events recorded corresponding page. Please review and update accordingly. else clarify' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 06:15:14
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:37:18
User entered 'No (N)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	09 Sep 2020 14:12:24
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	04 Sep 2020 13:23:09

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
	(b) (4)	
User entered 'USA-US032-2020-mRNA-1273-P301000019'	System	05 Dec 2020 15:28:52
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 15:28:52
User entered 'New' reason for change: New Information		05 Dec 2020 15:28:52
Reviewed for Safety.		05 Dec 2020 15:27:53
Un-reviewed for Safety.		05 Dec 2020 15:27:49
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4)	04 Dec 2020 15:21:40
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	09 Sep 2020 14:13:50
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:34:09
User entered 'USA-US032-2020-mRNA-1273-P301000001'	System	07 Sep 2020 18:34:02
User entered 'New'	(b) (4), (b) (6)	07 Sep 2020 18:34:02

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'PV Query:The event occurred before administration of IP or after administration of IP? If the event was detected/diagnosed before administration of IP, please confirm whether the event meets criteria of AE.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 20:22:17
User closed query 'PV Query: Subject was determined to be asymptomatic with a positive SARS-CoV-2 RT-PCR test. Per protocol, for a case to be considered valid, the subject must have a positive test result and have symptoms of COVID-19. Please determine if this case is valid.' (Site from Safety).		20 Jan 2021 20:22:15
Query 'PV Query:The event occurred before administration of IP or after administration of IP? If the event was detected/diagnosed before administration of IP, please confirm whether the event meets criteria of AE.' answered with 'swab was done on day of IP administration, results were not yet back. ' (Site from Safety).	Samantha Wieseler (b) (4)	19 Jan 2021 23:48:30
Query 'PV Query: Subject was determined to be asymptomatic with a positive SARS-CoV-2 RT-PCR test. Per protocol, for a case to be considered valid, the subject must have a positive test result and have symptoms of COVID-19. Please determine if this case is valid.' answered with 'case is valid' (Site from Safety).	Samantha Wieseler (b) (4)	19 Jan 2021 23:48:04
User opened query 'PV Query:The event occurred before administration of IP or after administration of IP? If the event was detected/diagnosed before administration of IP, please confirm whether the event meets criteria of AE.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 17:39:53
User opened query 'PV Query: Subject was determined to be asymptomatic with a positive SARS-CoV-2 RT-PCR test. Per protocol, for a case to be considered valid, the subject must have a positive test result and have symptoms of COVID-19. Please determine if this case is valid.' (Site from Safety).		19 Jan 2021 17:39:33

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'PV Query:The event occurred before administration of IP or after administration of IP? If the event was detected/diagnosed before administration of IP, please confirm whether the event meets criteria of AE.' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 15:10:08
Query 'PV Query:The event occurred before administration of IP or after administration of IP? If the event was detected/diagnosed before administration of IP, please confirm whether the event meets criteria of AE.' answered with 'Subjects nasal swab came back positive from first visit. ' (Site from Safety).	Samantha Wieseler (b) (4)	09 Jan 2021 16:33:58
User opened query 'PV Query:The event occurred before administration of IP or after administration of IP? If the event was detected/diagnosed before administration of IP, please confirm whether the event meets criteria of AE.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 14:10:29
User closed query 'PV Query:The event occurred before administration of IP or after administration of IP? If the event was detected/diagnosed before administration of IP, please confirm whether the event meets criteria of AE.' (Site from Safety).	(b) (4), (b) (6)	31 Dec 2020 00:51:57
Query 'PV Query:The event occurred before administration of IP or after administration of IP? If the event was detected/diagnosed before administration of IP, please confirm whether the event meets criteria of AE.' answered with 'subject's nasal swab came back positive from first visit' (Site from Safety).	Kelsey Kelley (b) (4)	29 Dec 2020 17:07:41
User opened query 'PV Query:The event occurred before administration of IP or after administration of IP? If the event was detected/diagnosed before administration of IP, please confirm whether the event meets criteria of AE.' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 14:33:04
User coded data point as SOC: Infections and infestations, HLT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: SARS-CoV-2 infection - version MedDRA\23.0.	Coder Import (b) (4)	11 Dec 2020 05:04:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	11 Dec 2020 05:04:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07

PRODUCTION RELEASE (v12.003
EAB) (1725)

1573 of 1790

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	04 Dec 2020 15:24:09
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 15:23:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 15:23:32
User entered 'SarsCov-2 Infection' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	04 Dec 2020 15:23:32
Data point term sent to Coder	System	04 Dec 2020 15:22:07
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4)	04 Dec 2020 15:21:40
Data point term sent to Coder	System	09 Sep 2020 14:14:23
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	09 Sep 2020 14:13:50
Data point term sent to Coder	System	09 Sep 2020 14:13:22
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 14:13:08
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4)	09 Sep 2020 14:13:08
User coded data point as SOC: Infections and infestations, HLT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: SARS-CoV-2 infection - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 13:26:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 13:26:41
Data point term sent to Coder	System	04 Sep 2020 13:25:14
User entered 'sars-cov-2 infection'	Kelsey Kelley (b) (4)	04 Sep 2020 13:25:09

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 15:23:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 15:23:32
User entered 'No (N)' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	04 Dec 2020 15:23:32
	(b) (4)	
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4)	04 Dec 2020 15:21:40
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	09 Sep 2020 14:13:50
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 14:13:08
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4)	09 Sep 2020 14:13:08
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	04 Sep 2020 13:25:09
	(b) (4)	

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 15:23:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 15:23:32
User entered 'No (N)' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	04 Dec 2020 15:23:32
	(b) (4)	
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4)	04 Dec 2020 15:21:40
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	09 Sep 2020 14:13:50
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 14:13:08
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4)	09 Sep 2020 14:13:08
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	04 Sep 2020 13:25:09
	(b) (4)	

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:51:20
	(b) (4)	
Signature has been broken.	Samantha Wieseler (b) (4)	28 Jan 2021 19:40:57
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	28 Jan 2021 19:40:57
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 15:23:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 15:23:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	04 Dec 2020 15:23:32
	(b) (4)	
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4)	04 Dec 2020 15:21:40
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	09 Sep 2020 14:13:50
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 14:13:08
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4)	09 Sep 2020 14:13:08
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	04 Sep 2020 13:25:09
	(b) (4)	

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 15:23:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 15:23:32
User entered '18 Aug 2020' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	04 Dec 2020 15:23:32
	(b) (4)	
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4)	04 Dec 2020 15:21:40
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	09 Sep 2020 14:13:50
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 14:13:08
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4)	09 Sep 2020 14:13:08
	(b) (4)	
User entered '18 Aug 2020'	Kelsey Kelley (b) (4)	04 Sep 2020 13:25:09
	(b) (4)	

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Dec 2020 15:24:06
User entered '08:00' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	04 Dec 2020 15:24:06
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Dec 2020 15:23:32
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4)	04 Dec 2020 15:21:40
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	09 Sep 2020 14:13:50
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	09 Sep 2020 14:13:08
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 13:25:09
User entered empty.	Kelsey Kelley (b) (4)	04 Sep 2020 13:25:09
	(b) (4)	

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 08:00'	System	04 Dec 2020 15:24:06
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4)	04 Dec 2020 15:21:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Linden DeBoer (b) (4)	09 Sep 2020 14:13:50
	(b) (4)	
User entered empty.	System	04 Sep 2020 13:25:09

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 15:23:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 15:23:32
User entered 'No (N)' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	04 Dec 2020 15:23:32
	(b) (4)	
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4)	04 Dec 2020 15:21:40
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	09 Sep 2020 14:13:50
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 14:13:08
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4)	09 Sep 2020 14:13:08
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	04 Sep 2020 13:25:09
	(b) (4)	

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User closed query 'PV Query: Please clarify how the event was determined to be resolved on 25Aug2020 considering that the subject was asymptomatic.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	11 Jan 2021 15:10:06
Query 'PV Query: Please clarify how the event was determined to be resolved on 25Aug2020 considering that the subject was asymptomatic.' answered with 'updated' (Site from Safety).	Samantha Wieseler (b) (4) (b) (4)	09 Jan 2021 16:34:29
Signature has been broken.	Samantha Wieseler (b) (4) (b) (4)	09 Jan 2021 16:34:21
User entered '18 Aug 2020' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	09 Jan 2021 16:34:21
User opened query 'PV Query: Please clarify how the event was determined to be resolved on 25Aug2020 considering that the subject was asymptomatic.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 14:13:45
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:07
User entered '25 Aug 2020' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	04 Dec 2020 15:23:32
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4) (b) (4)	04 Dec 2020 15:21:40
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4) (b) (4)	09 Sep 2020 14:13:50
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	09 Sep 2020 14:13:08
User entered '25 Aug 2020'	Kelsey Kelley (b) (4) (b) (4)	04 Sep 2020 13:25:09

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Dec 2020 15:24:06
User entered '08:01' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	04 Dec 2020 15:24:06
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Dec 2020 15:23:32
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4)	04 Dec 2020 15:21:40
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	09 Sep 2020 14:13:50
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	09 Sep 2020 14:13:08
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 13:25:09
User entered empty.	Kelsey Kelley (b) (4)	04 Sep 2020 13:25:09
	(b) (4)	

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 08:01'	System	09 Jan 2021 16:34:21
User entered '25 Aug 2020 08:01'	System	04 Dec 2020 15:24:06
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4) (b) (4)	04 Dec 2020 15:21:40
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4) (b) (4)	09 Sep 2020 14:13:50
User entered empty.	System	04 Sep 2020 13:25:09

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 15:23:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 15:23:32
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	04 Dec 2020 15:23:32
	(b) (4)	
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4)	04 Dec 2020 15:21:40
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	09 Sep 2020 14:13:50
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 13:25:09
User entered empty.	Kelsey Kelley (b) (4)	04 Sep 2020 13:25:09
	(b) (4)	

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 15:24:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 15:24:06
User entered 'No (N)' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	04 Dec 2020 15:24:06
	(b) (4)	
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4)	04 Dec 2020 15:21:40
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	09 Sep 2020 14:13:50
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 13:25:09
User entered empty.	Kelsey Kelley (b) (4)	04 Sep 2020 13:25:09
	(b) (4)	

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
	(b) (4)	
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4)	04 Dec 2020 15:21:40
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	09 Sep 2020 14:13:50
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	04 Sep 2020 13:25:09
	(b) (4)	

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
	(b) (4)	
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4)	04 Dec 2020 15:21:40
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	09 Sep 2020 14:13:50
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	04 Sep 2020 13:25:09
	(b) (4)	

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
	(b) (4)	
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4)	04 Dec 2020 15:21:40
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	09 Sep 2020 14:13:50
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	04 Sep 2020 13:25:09
	(b) (4)	

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
	(b) (4)	
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4)	04 Dec 2020 15:21:40
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	09 Sep 2020 14:13:50
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	04 Sep 2020 13:25:09
	(b) (4)	

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
	(b) (4)	
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4)	04 Dec 2020 15:21:40
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	09 Sep 2020 14:13:50
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	04 Sep 2020 13:25:09
	(b) (4)	

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
	(b) (4)	
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4)	04 Dec 2020 15:21:40
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	09 Sep 2020 14:13:50
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	04 Sep 2020 13:25:09
	(b) (4)	

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
	(b) (4)	
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4)	04 Dec 2020 15:21:40
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	09 Sep 2020 14:13:50
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	04 Sep 2020 13:25:09
	(b) (4)	

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
	(b) (4)	
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4)	04 Dec 2020 15:21:40
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	09 Sep 2020 14:13:50
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	04 Sep 2020 13:25:09
	(b) (4)	

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
	(b) (4)	
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4)	04 Dec 2020 15:21:40
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	09 Sep 2020 14:13:50
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	04 Sep 2020 13:25:09
	(b) (4)	

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
	(b) (4)	
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4)	04 Dec 2020 15:21:40
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	09 Sep 2020 14:13:50
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	04 Sep 2020 13:25:09
	(b) (4)	

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query ' PV Query: Please provide rationale why the event was assessed as Not applicable to IP and Not applicable to study procedure.' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 15:10:03
Query ' PV Query: Please provide rationale why the event was assessed as Not applicable to IP and Not applicable to study procedure.' answered with 'subject swab was performed before any IP was administered' (Site from Safety).	Samantha Wieseler (b) (4)	09 Jan 2021 16:38:51
User opened query ' PV Query: Please provide rationale why the event was assessed as Not applicable to IP and Not applicable to study procedure.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 14:10:54
User closed query ' PV Query: Please provide rationale why the event was assessed as Not applicable to IP and Not applicable to study procedure.' (Site from Safety).	(b) (4), (b) (6)	31 Dec 2020 00:51:53
Query ' PV Query: Please provide rationale why the event was assessed as Not applicable to IP and Not applicable to study procedure.' answered with 'subject's nasal swab came back positive from first visit' (Site from Safety).	Kelsey Kelley (b) (4)	29 Dec 2020 17:08:22
User opened query ' PV Query: Please provide rationale why the event was assessed as Not applicable to IP and Not applicable to study procedure.' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 14:33:43
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' canceled (Site from Safety).	(b) (4), (b) (6)	05 Dec 2020 15:23:54
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	04 Dec 2020 15:25:01
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	04 Dec 2020 15:24:06
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 15:23:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 15:23:32
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	04 Dec 2020 15:23:32

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4)	04 Dec 2020 15:21:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Linden DeBoer (b) (4)	09 Sep 2020 14:13:50
	(b) (4)	
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	07 Sep 2020 18:30:05
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 13:25:09
User entered empty.	Kelsey Kelley (b) (4)	04 Sep 2020 13:25:09
	(b) (4)	

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User closed query ' PV Query: Please provide rationale why the event was assessed as Not applicable to IP and Not applicable to study procedure.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	11 Jan 2021 15:10:00
Signature has been broken.	Samantha Wieseler (b) (4)	09 Jan 2021 16:39:36
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4)	
Query ' PV Query: Please provide rationale why the event was assessed as Not applicable to IP and Not applicable to study procedure.' answered with 'updated' (Site from Safety).	Samantha Wieseler (b) (4)	09 Jan 2021 16:39:36
	(b) (4)	
Query ' PV Query: Please provide rationale why the event was assessed as Not applicable to IP and Not applicable to study procedure.' answered with 'subject's nasal swab came back positive from first visit' (Site from Safety).	Samantha Wieseler (b) (4)	09 Jan 2021 16:39:29
	(b) (4)	
User opened query ' PV Query: Please provide rationale why the event was assessed as Not applicable to IP and Not applicable to study procedure.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 14:11:04
User closed query ' PV Query: Please provide rationale why the event was assessed as Not applicable to IP and Not applicable to study procedure.' (Site from Safety).	(b) (4), (b) (6)	31 Dec 2020 00:51:51
Query ' PV Query: Please provide rationale why the event was assessed as Not applicable to IP and Not applicable to study procedure.' answered with 'subject's nasal swab came back positive from first visit' (Site from Safety).	Kelsey Kelley (b) (4)	29 Dec 2020 17:08:26
	(b) (4)	
User opened query ' PV Query: Please provide rationale why the event was assessed as Not applicable to IP and Not applicable to study procedure.' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 14:33:59
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	04 Dec 2020 15:25:01
	(b) (4)	
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	04 Dec 2020 15:24:06
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 15:23:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 15:23:32

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	04 Dec 2020 15:23:32
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4)	04 Dec 2020 15:21:40
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	09 Sep 2020 14:13:50
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 13:25:09
User entered empty.	Kelsey Kelley (b) (4)	04 Sep 2020 13:25:09

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
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) (4), (b) (6)	07 Dec 2020 05:12:11
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 'IP withheld due to Covid positive' (Site from System).	Samantha Wieseler (b) (4) (b) (4)	04 Dec 2020 15:24:55
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	04 Dec 2020 15:21:40
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4) (b) (4)	04 Dec 2020 15:21:40
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4) (b) (4)	09 Sep 2020 14:13:50
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Kelsey Kelley (b) (4) (b) (4)	04 Sep 2020 13:25:09

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

None

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
	(b) (4)	
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4)	04 Dec 2020 15:21:40
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	09 Sep 2020 14:13:50
	(b) (4)	
User entered '1'	Kelsey Kelley (b) (4)	04 Sep 2020 13:25:09
	(b) (4)	

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

[Concomitant Medication](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 14:17:30
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 14:09:50
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
DataPoint activated with code reason code Data required.	(b) (4)	
	Samantha Wieseler (b) (4)	04 Dec 2020 15:21:40
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	09 Sep 2020 14:13:50
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	04 Sep 2020 13:25:09
	(b) (4)	

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
	(b) (4)	
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4)	04 Dec 2020 15:21:40
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	09 Sep 2020 14:13:50
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	04 Sep 2020 13:25:09
	(b) (4)	

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 15:23:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 15:23:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	04 Dec 2020 15:23:32
	(b) (4)	
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4)	04 Dec 2020 15:21:40
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	09 Sep 2020 14:13:50
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 14:13:08
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4)	09 Sep 2020 14:13:08
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Kelsey Kelley (b) (4)	04 Sep 2020 13:25:09
	(b) (4)	

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
	(b) (4)	
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4)	04 Dec 2020 15:21:40
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	09 Sep 2020 14:13:50
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	04 Sep 2020 13:25:09
	(b) (4)	

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 15:09:57
User closed query 'Please confirm if this remain valid event as patient was asymptomatic?' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 15:09:56
Query 'Please confirm if this remain valid event as patient was asymptomatic?' answered with 'still valid event as subject still had Covid-19 was just asymptomatic' (Site from Safety).	Samantha Wieseler (b) (4)	(b) (4) 09 Jan 2021 16:43:33
Query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' answered with 'will update accordingly' (Site from Safety).	Samantha Wieseler (b) (4)	(b) (4) 09 Jan 2021 16:43:10
User opened query 'Please confirm if this remain valid event as patient was asymptomatic?' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 14:11:38
User opened query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 14:09:19
User closed query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' (Site from Safety).	(b) (4), (b) (6)	31 Dec 2020 00:51:49
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	31 Dec 2020 00:51:47

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'None taken as subject was asymptomatic ' (Site from Safety).	Kelsey Kelley (b) (4)	29 Dec 2020 17:09:16
Query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' answered with 'subject's nasal swab came back positive from first visit. She was asymptomatic' (Site from Safety).	Kelsey Kelley (b) (4)	29 Dec 2020 17:08:48
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 14:32:06
User opened query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 14:31:50
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Samantha Wieseler (b) (4)	04 Dec 2020 15:21:40
User entered empty.	(b) (4)	
	Linden DeBoer (b) (4)	09 Sep 2020 14:13:50
	(b) (4)	
	Kelsey Kelley (b) (4)	04 Sep 2020 13:25:09
	(b) (4)	

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	04 Dec 2020 15:24:06
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4) (b) (4)	04 Dec 2020 15:21:40
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4) (b) (4)	09 Sep 2020 14:13:50

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4)	04 Dec 2020 15:21:40
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	09 Sep 2020 14:13:50
User entered '0'	System	04 Sep 2020 13:25:09

US3032211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:47

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4)	04 Dec 2020 15:21:40
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	09 Sep 2020 14:13:50

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 21:53:47

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:54:35
DataPoint Verified.		17 Dec 2020 18:24:10
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:33:02

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:47

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 22:32:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 22:32:50
Data point term sent to Coder	System	18 Aug 2020 18:34:29
User entered 'Levothyroxine'	Kelsey Kelley (b) (4)	18 Aug 2020 18:33:41

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:47

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	18 Aug 2020 18:33:41
	(b) (4)	

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:47

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'medical history: hypothyroidism'	(b) (4) Kelsey Kelley (b) (4)	18 Aug 2020 18:33:41

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:39:10
	(b) (4)	
Signature has been broken.	Linden DeBoer (b) (4)	22 Mar 2021 21:42:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
	(b) (4)	
User entered '75'	Kelsey Kelley (b) (4)	18 Aug 2020 18:33:41
	(b) (4)	

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:47

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User closed query 'Per DM CLR: Please review Unit = Other (MCG) and verify if one of the available unit options (e.g. ug, etc.) would be applicable. Please review and update to select the appropriate unit rather than to select Other. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 11:37:37
Query 'Per DM CLR: Please review Unit = Other (MCG) and verify if one of the available unit options (e.g. ug, etc.) would be applicable. Please review and update to select the appropriate unit rather than to select Other. Otherwise, clarify. ' answered with 'data updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:56:40
User entered 'ug (ug)' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	18 Sep 2020 15:56:32
User opened query 'Per DM CLR: Please review Unit = Other (MCG) and verify if one of the available unit options (e.g. ug, etc.) would be applicable. Please review and update to select the appropriate unit rather than to select Other. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 07:42:48
User entered 'Other (OTHER)'	Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:33:41

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:47

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty; reason for change Data Entry Error	(b) (4)	18 Sep 2020 15:56:32
User entered 'mcg'	Kelsey Kelley (b) (4)	18 Aug 2020 18:33:41
	(b) (4)	

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:47

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4)	18 Aug 2020 18:33:41

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:47

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:39:10
	(b) (4)	
Signature has been broken.	Linden DeBoer (b) (4)	22 Mar 2021 21:42:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	18 Aug 2020 18:33:41
	(b) (4)	

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:47

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4)	18 Aug 2020 18:33:41

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:47

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	18 Aug 2020 18:33:41
	(b) (4)	

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:56:03
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	18 Aug 2020 18:33:41
User entered 'un UNK 2018'	Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:33:41

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	18 Aug 2020 18:33:41

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:47

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	18 Aug 2020 18:33:41
	(b) (4)	

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	18 Aug 2020 18:33:41
	(b) (4)	

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	18 Aug 2020 18:33:41

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 18:33:41

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 18:33:41

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 18:33:41

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:47

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Aug 2020 22:32:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 22:32:50
Data point term sent to Coder	System	18 Aug 2020 18:34:30
User entered 'sertraline'	Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:34:11

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:47

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	18 Aug 2020 18:34:11

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:47

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'medical history: depression'	(b) (4) Kelsey Kelley (b) (4)	18 Aug 2020 18:34:11

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:47

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '50'	(b) (4) Kelsey Kelley (b) (4)	18 Aug 2020 18:34:11

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:47

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	18 Aug 2020 18:34:11

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:47

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	18 Aug 2020 18:34:11
	(b) (4)	

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:47

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'once daily (QD)'	Kelsey Kelley (b) (4)	18 Aug 2020 18:34:11

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	18 Aug 2020 18:34:11
	(b) (4)	

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:47

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4)	18 Aug 2020 18:34:11

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:47

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	Kelsey Kelley (b) (4)	18 Aug 2020 18:34:11

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:56:21
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	18 Aug 2020 18:34:11
User entered 'un UNK 2018'	Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:34:11

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	18 Aug 2020 18:34:11

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:47

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	18 Aug 2020 18:34:11
	(b) (4)	

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	18 Aug 2020 18:34:11
	(b) (4)	

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	18 Aug 2020 18:34:11

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 18:34:11

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 18:34:11

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 18:34:11

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:38:21
DataPoint Verified.		17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:56:35
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.	(b) (4) Coder Import (b) (4)	09 Oct 2020 14:29:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 14:29:39
Data point term sent to Coder	System	08 Oct 2020 21:54:39
User entered 'seasonal flu vaccine'	Kelsey Kelley (b) (4)	08 Oct 2020 21:53:39

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:38:21
DataPoint Verified.		17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:56:35
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 21:53:39

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:38:21
DataPoint Verified.		17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:56:35
User entered 'prevention of seasonal flu'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 21:53:39

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:38:21
DataPoint Verified.		17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:56:35
User entered '0.5'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 21:53:39

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:38:21
DataPoint Verified.		17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:56:35
User entered 'mL (mL)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 21:53:39

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:38:21
DataPoint Verified.		17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:56:35
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 21:53:39

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:38:21
DataPoint Verified.		17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:56:35
User entered 'once (ONCE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 21:53:39

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:38:21
DataPoint Verified.		17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:56:35
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 21:53:39

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:38:21
DataPoint Verified.		17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:56:35
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 21:53:39

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:38:21
DataPoint Verified.		17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:56:35
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 21:53:39

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:38:21
DataPoint Verified.		17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:56:35
User entered '02 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 21:53:39

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:38:21
DataPoint Verified.		17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:56:35
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 21:53:39

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:38:21
DataPoint Verified.		17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:56:35
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 21:53:39

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:38:21
DataPoint Verified.		17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:56:35
User entered '02 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 21:53:39

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:38:21
DataPoint Verified.		17 Dec 2020 18:24:05
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:56:35
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	08 Oct 2020 21:53:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Oct 2020 21:53:44
User entered 'No (N)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	08 Oct 2020 21:53:44
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Oct 2020 21:53:39
User entered empty.	Kelsey Kelley (b) (4)	08 Oct 2020 21:53:39
	(b) (4)	

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:38:21
User entered empty.	System	08 Oct 2020 21:53:39

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:38:21
User entered empty.	System	08 Oct 2020 21:53:39

US3032211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:38:21
User entered empty.	System	08 Oct 2020 21:53:39

US3032211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 21:53:47

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:34:20

US3032211

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:53:47

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:59:18
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
User entered '17 Sep 2020'	(b) (4)	
	Russell Herstein (b) (4)	01 Dec 2020 17:13:37
	(b) (4)	

US3032211

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:53:47

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:59:18
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
User entered 'Due to SARS-COV-2 (COVID)'	(b) (4) Russell Herstein (b) (4)	01 Dec 2020 17:13:37

US3032211

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:53:47

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 04:59:18
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
User entered empty.	(b) (4) Russell Herstein (b) (4)	01 Dec 2020 17:13:37

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Sep 2020 18:39:01
User entered 'USA-US032-2020-MRNA-1273-P301000001'	System	07 Sep 2020 18:34:02

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Sep 2020 18:39:01
User entered 'No (N)'	System	07 Sep 2020 18:34:02

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Sep 2020 18:39:01
User entered 'No (N)'	System	07 Sep 2020 18:34:02

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Sep 2020 18:39:01
User entered 'No (N)'	System	07 Sep 2020 18:34:02

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Sep 2020 18:39:01
User entered 'No (N)'	System	07 Sep 2020 18:34:02

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Sep 2020 18:39:01
User entered 'No (N)'	System	07 Sep 2020 18:34:02

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Sep 2020 18:39:01
User entered 'No (N)'	System	07 Sep 2020 18:34:02

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Sep 2020 18:39:01
User entered 'No (N)'	System	07 Sep 2020 18:34:02

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 12:44:26
User entered 'Keith'	Linden DeBoer (b) (4) (b) (4)	10 Sep 2020 16:18:37

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 12:44:26
User entered 'Vrbicky'	Linden DeBoer (b) (4) (b) (4)	10 Sep 2020 16:18:37

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:11:05
Un-reviewed for Safety.	System	04 Dec 2020 15:21:40
Signature has been broken.	System	04 Dec 2020 15:21:40
User entered empty.	System	04 Dec 2020 15:21:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 12:44:26
User entered '1410 N 13th St'	Linden DeBoer (b) (4) (b) (4)	10 Sep 2020 16:18:37

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:11:05
Un-reviewed for Safety.	System	04 Dec 2020 15:21:40
Signature has been broken.	System	04 Dec 2020 15:21:40
User entered empty.	System	04 Dec 2020 15:21:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 12:44:26
User entered 'Norfolk'	Linden DeBoer (b) (4) (b) (4)	10 Sep 2020 16:18:37

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:11:05
Un-reviewed for Safety.	System	04 Dec 2020 15:21:40
Signature has been broken.	System	04 Dec 2020 15:21:40
User entered empty.	System	04 Dec 2020 15:21:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 12:44:26
User entered 'Nebraska'	Linden DeBoer (b) (4) (b) (4)	10 Sep 2020 16:18:37

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:11:05
Un-reviewed for Safety.	System	04 Dec 2020 15:21:40
Signature has been broken.	System	04 Dec 2020 15:21:40
User entered empty.	System	04 Dec 2020 15:21:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 12:44:26
User entered '68701'	Linden DeBoer (b) (4) (b) (4)	10 Sep 2020 16:18:37

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
	(b) (4)	
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:18:31
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:44:26
User entered 'US' (non-conformant).	System	07 Sep 2020 18:39:07

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
	(b) (4)	
Signature has been broken.	System	05 Dec 2020 15:11:00
User entered '2'	System	05 Dec 2020 15:11:00
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
	(b) (4)	
User entered '1'	System	07 Sep 2020 18:39:07

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Sep 2020 18:39:01
User entered 'USA-US032-2020-MRNA-1273-P301000001'	System	07 Sep 2020 18:34:02

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Sep 2020 18:39:01
User entered 'No (N)'	System	07 Sep 2020 18:34:02

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Sep 2020 18:39:01
User entered 'No (N)'	System	07 Sep 2020 18:34:02

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Sep 2020 18:39:01
User entered 'No (N)'	System	07 Sep 2020 18:34:02

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Sep 2020 18:39:01
User entered 'No (N)'	System	07 Sep 2020 18:34:02

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Sep 2020 18:39:01
User entered 'No (N)'	System	07 Sep 2020 18:34:02

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Sep 2020 18:39:01
User entered 'No (N)'	System	07 Sep 2020 18:34:02

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Sep 2020 18:39:01
User entered 'No (N)'	System	07 Sep 2020 18:34:02

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 12:44:26
User entered 'Keith'	Linden DeBoer (b) (4) (b) (4)	10 Sep 2020 16:18:37

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 12:44:26
User entered 'Vrbicky'	Linden DeBoer (b) (4) (b) (4)	10 Sep 2020 16:18:37

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:11:05
Un-reviewed for Safety.	System	04 Dec 2020 15:21:40
Signature has been broken.	System	04 Dec 2020 15:21:40
User entered empty.	System	04 Dec 2020 15:21:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 12:44:26
User entered '1410 N 13th St'	Linden DeBoer (b) (4) (b) (4)	10 Sep 2020 16:18:37

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:11:05
Un-reviewed for Safety.	System	04 Dec 2020 15:21:40
Signature has been broken.	System	04 Dec 2020 15:21:40
User entered empty.	System	04 Dec 2020 15:21:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 12:44:26
User entered 'Norfolk'	Linden DeBoer (b) (4) (b) (4)	10 Sep 2020 16:18:37

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:11:05
Un-reviewed for Safety.	System	04 Dec 2020 15:21:40
Signature has been broken.	System	04 Dec 2020 15:21:40
User entered empty.	System	04 Dec 2020 15:21:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 12:44:26
User entered 'Nebraska'	Linden DeBoer (b) (4) (b) (4)	10 Sep 2020 16:18:37

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:11:05
Un-reviewed for Safety.	System	04 Dec 2020 15:21:40
Signature has been broken.	System	04 Dec 2020 15:21:40
User entered empty.	System	04 Dec 2020 15:21:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 12:44:26
User entered '68701'	Linden DeBoer (b) (4) (b) (4)	10 Sep 2020 16:18:37

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
	(b) (4)	
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:18:31
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:44:26
User entered 'US' (non-conformant).	System	07 Sep 2020 18:39:07

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
	(b) (4)	
Signature has been broken.	System	05 Dec 2020 15:11:00
User entered '2'	System	05 Dec 2020 15:11:00
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
	(b) (4)	
User entered '1'	System	07 Sep 2020 18:39:07

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 21:53:47

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
User entered '07/Sep/2020 14:39'	(b) (4) System	07 Sep 2020 18:39:07

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 21:53:47

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.

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 12:44:26
User entered 'I'	(b) (4), (b) (6)	07 Sep 2020 18:39:07

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Sep 2020 18:39:01
User entered 'USA-US032-2020-MRNA-1273-P301000001'	System	07 Sep 2020 18:34:02

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Sep 2020 18:39:01
User entered 'No (N)'	System	07 Sep 2020 18:34:02

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Sep 2020 18:39:01
User entered 'No (N)'	System	07 Sep 2020 18:34:02

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Sep 2020 18:39:01
User entered 'No (N)'	System	07 Sep 2020 18:34:02

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Sep 2020 18:39:01
User entered 'No (N)'	System	07 Sep 2020 18:34:02

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Sep 2020 18:39:01
User entered 'No (N)'	System	07 Sep 2020 18:34:02

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Sep 2020 18:39:01
User entered 'No (N)'	System	07 Sep 2020 18:34:02

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Sep 2020 18:39:01
User entered 'No (N)'	System	07 Sep 2020 18:34:02

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 12:44:26
User entered 'Keith'	Linden DeBoer (b) (4) (b) (4)	10 Sep 2020 16:18:37

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 12:44:26
User entered 'Vrbicky'	Linden DeBoer (b) (4) (b) (4)	10 Sep 2020 16:18:37

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:11:05
Un-reviewed for Safety.	System	04 Dec 2020 15:21:40
Signature has been broken.	System	04 Dec 2020 15:21:40
User entered empty.	System	04 Dec 2020 15:21:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 12:44:26
User entered '1410 N 13th St'	Linden DeBoer (b) (4) (b) (4)	10 Sep 2020 16:18:37

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:11:05
Un-reviewed for Safety.	System	04 Dec 2020 15:21:40
Signature has been broken.	System	04 Dec 2020 15:21:40
User entered empty.	System	04 Dec 2020 15:21:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 12:44:26
User entered 'Norfolk'	Linden DeBoer (b) (4) (b) (4)	10 Sep 2020 16:18:37

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:11:05
Un-reviewed for Safety.	System	04 Dec 2020 15:21:40
Signature has been broken.	System	04 Dec 2020 15:21:40
User entered empty.	System	04 Dec 2020 15:21:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 12:44:26
User entered 'Nebraska'	Linden DeBoer (b) (4) (b) (4)	10 Sep 2020 16:18:37

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:11:05
Un-reviewed for Safety.	System	04 Dec 2020 15:21:40
Signature has been broken.	System	04 Dec 2020 15:21:40
User entered empty.	System	04 Dec 2020 15:21:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 12:44:26
User entered '68701'	Linden DeBoer (b) (4) (b) (4)	10 Sep 2020 16:18:37

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
	(b) (4)	
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:18:31
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:44:26
User entered 'US' (non-conformant).	System	07 Sep 2020 18:39:07

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
	(b) (4)	
Signature has been broken.	System	05 Dec 2020 15:11:00
User entered '2'	System	05 Dec 2020 15:11:00
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:37:18
	(b) (4)	
User entered '1'	System	07 Sep 2020 18:39:07

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 21:53:47

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
User entered '05/Dec/2020 15:10'	(b) (4) System	05 Dec 2020 15:11:00

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 21:53:47

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.

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Un-reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:27
User entered '0' reason for change: Data Entry Error		05 Dec 2020 15:29:27
Reviewed for Safety.		05 Dec 2020 15:11:05
User entered '1'		05 Dec 2020 15:11:00

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'USA-US032-2020-MRNA-1273-P301000019'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'No (N)'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'No (N)'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'No (N)'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'No (N)'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'No (N)'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'No (N)'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'No (N)'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'Keith'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'Vrbicky'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	31 Dec 2020 00:52:06
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
User entered 'US'	(b) (4) System	05 Dec 2020 15:29:51

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:51:20
	(b) (4)	
Signature has been broken.	System	20 Jan 2021 20:22:54
User entered '4'	System	20 Jan 2021 20:22:54
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
	(b) (4)	
Signature has been broken.	System	11 Jan 2021 15:14:46
User entered '3'	System	11 Jan 2021 15:14:46
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:25
	(b) (4)	
Signature has been broken.	System	31 Dec 2020 00:52:15
User entered '2'	System	31 Dec 2020 00:52:15
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
	(b) (4)	
User entered '1'	System	05 Dec 2020 15:29:51

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'USA-US032-2020-MRNA-1273-P301000019'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'No (N)'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'No (N)'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'No (N)'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'No (N)'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'No (N)'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'No (N)'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'No (N)'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'Keith'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'Vrbicky'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	31 Dec 2020 00:52:06
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
User entered 'US'	(b) (4) System	05 Dec 2020 15:29:51

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:51:20
	(b) (4)	
Signature has been broken.	System	20 Jan 2021 20:22:54
User entered '4'	System	20 Jan 2021 20:22:54
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
	(b) (4)	
Signature has been broken.	System	11 Jan 2021 15:14:46
User entered '3'	System	11 Jan 2021 15:14:46
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:25
	(b) (4)	
Signature has been broken.	System	31 Dec 2020 00:52:15
User entered '2'	System	31 Dec 2020 00:52:15
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
	(b) (4)	
User entered '1'	System	05 Dec 2020 15:29:51

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 21:53:47

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
User entered '05/Dec/2020 15:29'	(b) (4) System	05 Dec 2020 15:29:51

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 21:53:47

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.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	31 Dec 2020 00:52:06
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
User entered 'I'	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:51

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'USA-US032-2020-MRNA-1273-P301000019'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'No (N)'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'No (N)'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'No (N)'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'No (N)'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'No (N)'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'No (N)'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'No (N)'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'Keith'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'Vrbicky'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	31 Dec 2020 00:52:06
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
User entered 'US'	(b) (4) System	05 Dec 2020 15:29:51

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:51:20
	(b) (4)	
Signature has been broken.	System	20 Jan 2021 20:22:54
User entered '4'	System	20 Jan 2021 20:22:54
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
	(b) (4)	
Signature has been broken.	System	11 Jan 2021 15:14:46
User entered '3'	System	11 Jan 2021 15:14:46
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:25
	(b) (4)	
Signature has been broken.	System	31 Dec 2020 00:52:15
User entered '2'	System	31 Dec 2020 00:52:15
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
	(b) (4)	
User entered '1'	System	05 Dec 2020 15:29:51

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 21:53:47

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:25
User entered '31/Dec/2020 00:52'	(b) (4) System	31 Dec 2020 00:52:15

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 21:53:47

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.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 15:14:36
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:25
User entered 'I'	(b) (4) (b) (4), (b) (6)	31 Dec 2020 00:52:15

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'USA-US032-2020-MRNA-1273-P301000019'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'No (N)'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'No (N)'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'No (N)'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'No (N)'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'No (N)'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'No (N)'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'No (N)'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'Keith'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'Vrbicky'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	31 Dec 2020 00:52:06
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
User entered 'US'	(b) (4) System	05 Dec 2020 15:29:51

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:51:20
	(b) (4)	
Signature has been broken.	System	20 Jan 2021 20:22:54
User entered '4'	System	20 Jan 2021 20:22:54
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
	(b) (4)	
Signature has been broken.	System	11 Jan 2021 15:14:46
User entered '3'	System	11 Jan 2021 15:14:46
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:25
	(b) (4)	
Signature has been broken.	System	31 Dec 2020 00:52:15
User entered '2'	System	31 Dec 2020 00:52:15
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
	(b) (4)	
User entered '1'	System	05 Dec 2020 15:29:51

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 21:53:47

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered '11/Jan/2021 15:14'	(b) (4) System	11 Jan 2021 15:14:46

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 21:53:47

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.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 20:22:40
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
User entered 'I'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 15:14:46

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'USA-US032-2020-MRNA-1273-P301000019'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'No (N)'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'No (N)'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'No (N)'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'No (N)'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'No (N)'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'No (N)'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'No (N)'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'Keith'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 15:29:41
User entered 'Vrbicky'	System	05 Dec 2020 15:28:52

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	31 Dec 2020 00:52:06
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
User entered 'US'	(b) (4) System	05 Dec 2020 15:29:51

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:51:20
	(b) (4)	
Signature has been broken.	System	20 Jan 2021 20:22:54
User entered '4'	System	20 Jan 2021 20:22:54
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:45
	(b) (4)	
Signature has been broken.	System	11 Jan 2021 15:14:46
User entered '3'	System	11 Jan 2021 15:14:46
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:25
	(b) (4)	
Signature has been broken.	System	31 Dec 2020 00:52:15
User entered '2'	System	31 Dec 2020 00:52:15
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:17
	(b) (4)	
User entered '1'	System	05 Dec 2020 15:29:51

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 21:53:47

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:51:20
User entered '20/Jan/2021 20:22'	(b) (4) System	20 Jan 2021 20:22:54

US3032211

Folder: SAE USA-US032-2020-MRNA-1273-P301000019

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 21:53:47

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.

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:51:20
User entered 'I'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:22:54