

US3312201 (Prod: Johnson County Clin-Trials)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:16:12

All time stamps listed in this document are displayed in GMT

US3312201

Form: Participant Creation

Data signed: (b) (4) 05 Apr 2021 21:16:13

Generated On: 11 Aug 2021 22:16:12

Participant ID

US3312201

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

US3312201

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:07:11

Generated On: 11 Aug 2021 22:16:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3312201

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 22:07:10

Generated On: 11 Aug 2021 22:16:12

Date of Birth (MMM yyyy)	(b) (6) 1954
Age	65
Age Units	YEARS
Age (Derived)	65
Sex	Female <input type="radio"/> Male <input checked="" 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

US3312201

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 22:07:10

Generated On: 11 Aug 2021 22:16:12

Date of Informed Consent (<i>dd MMM yyyy</i>)	20 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

US3312201

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 22:07:11

Generated On: 11 Aug 2021 22:16:12

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3312201

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 22:07:11

Generated On: 11 Aug 2021 22:16:12

Were any significant conditions reported?

Yes ☒

No ☐

US3312201

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 22:07:11

Generated On: 11 Aug 2021 22:16:12

Condition	CERVICAL FRACTURE
Start date (dd MMM yyyy)	UN UNK 2001
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2001
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	JAN 2001
Stop Year (derived)	2001

US3312201

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 22:07:11

Generated On: 11 Aug 2021 22:16:12

Condition	CERVICAL FUSION
Start date (dd MMM yyyy)	UN UNK 2001
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2001
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	JAN 2001
Stop Year (derived)	2001

US3312201

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 22:07:11

Generated On: 11 Aug 2021 22:16:12

Condition	HERNIATED L2, L3, L4, L5 DISC
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

US3312201

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 22:07:11

Generated On: 11 Aug 2021 22:16:12

Condition	LUMBAR FUSION L2-L5
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

US3312201

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 22:07:11

Generated On: 11 Aug 2021 22:16:12

Condition	BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

US3312201

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 22:07:11

Generated On: 11 Aug 2021 22:16:12

Condition	INTERMITTENT ABDOMINAL PAIN
Start date (dd MMM yyyy)	UN MAY 2020
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)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3312201

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 22:07:11

Generated On: 11 Aug 2021 22:16:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 AUG 2020
Time of assessment (00:00-23:59)	15:09 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 15:09
Height (xxx.x)	72 in
Weight (xxx.x)	226 lb
BMI (xxx.x)	30.71520 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input checked="" 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)	

US3312201

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:07:11

Generated On: 11 Aug 2021 22:16:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 AUG 2020

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

US3312201

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 22:07:11

Generated On: 11 Aug 2021 22:16:12

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3312201

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 22:07:11

Generated On: 11 Aug 2021 22:16:12

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	True
Specify	RESIDES IN COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION

US3312201

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:07:11

Generated On: 11 Aug 2021 22:16:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 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

US3312201

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 22:07:11

Generated On: 11 Aug 2021 22:16:12

What was the date of randomization? (dd MMM yyyy) 20 AUG 2020

What was the participant's randomization number? 187335

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 ☒

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 22:07:11

Generated On: 11 Aug 2021 22:16:12

Height	ND - Not Done
Weight	ND - Not Done

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 22:07:11

Generated On: 11 Aug 2021 22:16:12

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)	20 AUG 2020
Time of assessment (00:00-23:59)	15:09 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 15:09
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 22:07:11

Generated On: 11 Aug 2021 22:16:12

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	20 AUG 2020
Time of assessment (00:00-23:59)	16:42 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 16:42
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	93 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	101 mmHg
Diastolic Blood Pressure units	MMHG

US3312201

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:07:11

Generated On: 11 Aug 2021 22:16:12

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.

US3312201

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 22:07:11

Generated On: 11 Aug 2021 22:16:12

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) 20 AUG 2020

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

Treatment Date and Time (derived) 20 AUG 2020 16:06

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

What was the frequency of the study treatment dosing? ONCE

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

US3312201

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:07:11

Generated On: 11 Aug 2021 22:16:12

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	20 AUG 2020
Collection time (00:00-23:59)	15:37 (24 HR)
Collection date and time (derived)	20 AUG 2020 15:37

US3312201

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 22:07:11

Generated On: 11 Aug 2021 22:16:12

Collection date (dd MMM yyyy)			20 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:30	20 AUG 2020 15:30
Nasopharyngeal Swab 2	No		

US3312201

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:07:11

Generated On: 11 Aug 2021 22:16:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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 16:45

PC Open Date & Time

20 AUG 2020 16:26

PC Close Date & Time

20 AUG 2020 18:56

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:16:12

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 98.2 °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	20 AUG 2020 22:33
PC Open Date & Time	20 AUG 2020 19:51
PC Close Date & Time	21 AUG 2020 11:59

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:16:12

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 23:19

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

22 AUG 2020 20:50

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:16:12

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 21:18

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 21:15

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:16:12

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

99.3 °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

26 AUG 2020 00:10

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 00:01

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 16:46

PC Open Date & Time

20 AUG 2020 16:26

PC Close Date & Time

20 AUG 2020 18:56

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:16:12

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

20 AUG 2020 22:35

PC Open Date & Time

20 AUG 2020 19:51

PC Close Date & Time

21 AUG 2020 11:59

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:16:12

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

21 AUG 2020 23:20

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:16:12

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

22 AUG 2020 20:50

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:16:12

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

23 AUG 2020 21:19

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:16:12

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

24 AUG 2020 21:16

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:16:12

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

26 AUG 2020 00:11

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:16:12

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

27 AUG 2020 00:02

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:16:12

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 ☐

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:16:12

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 16:46
PC Open Date & Time	20 AUG 2020 16:26
PC Close Date & Time	20 AUG 2020 18:56

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:16:12

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 ☐

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:16:12

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 22:34
PC Open Date & Time	20 AUG 2020 19:51
PC Close Date & Time	21 AUG 2020 11:59

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:16:12

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 ☒

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:16:12

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 23:20
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:16:12

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
EAB) (1725)

49 of 1916

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:16:12

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 20:51
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:16:12

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 ☒

PRODUCTION RELEASE (v12.003

51 of 1916

EAB) (1725)

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:16:12

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 21:20
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:16:12

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 ☒

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:16:12

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 21:17
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:16:12

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 ☒

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:16:12

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

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:16:12

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 ☒

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:16:12

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 00:02
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3312201

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:07:10

Generated On: 11 Aug 2021 22:16:12

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

US3312201

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:07:10

Generated On: 11 Aug 2021 22:16:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312201

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:07:10

Generated On: 11 Aug 2021 22:16:12

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

US3312201

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:07:10

Generated On: 11 Aug 2021 22:16:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312201

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:07:10

Generated On: 11 Aug 2021 22:16:12

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

US3312201

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:07:10

Generated On: 11 Aug 2021 22:16:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312201

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:07:12

Generated On: 11 Aug 2021 22:16:12

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

US3312201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 22:07:12

Generated On: 11 Aug 2021 22:16:12

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)	14:29 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 14:29
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	98 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

US3312201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 22:07:12

Generated On: 11 Aug 2021 22:16:12

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

US3312201

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:07:12

Generated On: 11 Aug 2021 22:16:12

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.

US3312201

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 22:07:12

Generated On: 11 Aug 2021 22:16:12

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?

US3312201

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:07:12

Generated On: 11 Aug 2021 22:16:12

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

Collection date (dd MMM yyyy)	17 SEP 2020
-------------------------------	-------------

Collection time (00:00-23:59)	14:56 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	17 SEP 2020 14:56
------------------------------------	-------------------

US3312201

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 22:07:12

Generated On: 11 Aug 2021 22:16:12

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	14:50	17 SEP 2020 14:50
Nasopharyngeal Swab 2	No		

US3312201

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:07:12

Generated On: 11 Aug 2021 22:16:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312201

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:07:10

Generated On: 11 Aug 2021 22:16:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312201

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:07:10

Generated On: 11 Aug 2021 22:16:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312201

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:07:10

Generated On: 11 Aug 2021 22:16:12

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

US3312201

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:07:10

Generated On: 11 Aug 2021 22:16:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312201

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:07:10

Generated On: 11 Aug 2021 22:16:12

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

US3312201

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:07:10

Generated On: 11 Aug 2021 22:16:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312201

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:07:34

Generated On: 11 Aug 2021 22:16:12

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

US3312201

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 22:07:34

Generated On: 11 Aug 2021 22:16:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 OCT 2020
Time of assessment (00:00-23:59)	11:51 (24 HR)
Vital Signs Date and Time (derived)	28 OCT 2020 11:51
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	93 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	175 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	109 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312201

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:07:34

Generated On: 11 Aug 2021 22:16:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 OCT 2020

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

US3312201

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:07:34

Generated On: 11 Aug 2021 22:16:12

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 OCT 2020

Collection time (00:00-23:59)

12:39 (24 HR)

Collection date and time (derived)

28 OCT 2020 12:39

US3312201

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:07:12

Generated On: 11 Aug 2021 22:16:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	23 OCT 2020 14:45:04
Patient Cloud Open Date & Time	20 OCT 2020 00:01
Patient Cloud Close Date & Time	24 OCT 2020 23:59

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 OCT 2020 09:24:22

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 NOV 2020 20:33:39

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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"/>

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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"/>

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2020 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

DAY 103

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

28 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 DEC 2020 13:25:43
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 DEC 2020 10:52:08
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 DEC 2020 18:25:34
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 DEC 2020 13:04:04
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 JAN 2021 10:44:20

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 JAN 2021 22:37:02
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

16 JAN 2021 00:07:26

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

23 JAN 2021 12:37:25

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 FEB 2021 12:00:46
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

08 FEB 2021 10:18:24

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 FEB 2021 01:50:00
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

20 FEB 2021 09:08:13

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 00:02:58

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 MAR 2021 01:25:26
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

15 MAR 2021 13:27:41

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 MAR 2021 16:39:55

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	28 MAR 2021 23:35:39
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 APR 2021 00:44:44
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

12 APR 2021 11:45:44

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 10:26:42

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 19:08:39

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

02 MAY 2021 13:50:55

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐
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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐ 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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐
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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐ 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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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"/>

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐
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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	10 JUL 2021 00:01
Patient Cloud Close Date & Time	14 JUL 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐ 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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐
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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐
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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐ 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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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"/>

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐
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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	11 SEP 2021 00:01
Patient Cloud Close Date & Time	15 SEP 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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°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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐
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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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"/>

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐
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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐ 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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	16 OCT 2021 00:01
Patient Cloud Close Date & Time	20 OCT 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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°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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐ 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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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"/>

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐ 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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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"/>

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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"/>

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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"/>

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐
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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐ 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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐ 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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐ 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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐ 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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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°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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐
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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐ 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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐ 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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐ 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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐ 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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐
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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐ 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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐
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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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°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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐ 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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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"/>

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐ 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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐ 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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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"/>

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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"/>

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐ 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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐ 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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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"/>

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐ 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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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 ☐ 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 ☐

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2022 23:59

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3312201

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:16:12

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 13:09:56

US3312201

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:16:13

Generated On: 11 Aug 2021 22:16:12

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3312201

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:16:13

Generated On: 11 Aug 2021 22:16:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312201

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:16:13

Generated On: 11 Aug 2021 22:16:12

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3312201

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:16:13

Generated On: 11 Aug 2021 22:16:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312201

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:16:13

Generated On: 11 Aug 2021 22:16:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312201

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:16:13

Generated On: 11 Aug 2021 22:16:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312201

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:16:13

Generated On: 11 Aug 2021 22:16:12

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

US3312201

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:16:13

Generated On: 11 Aug 2021 22:16:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312201

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 21:16:54

Generated On: 11 Aug 2021 22:16:12

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

Visit date (dd MMM yyyy)	10 MAR 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
------------	--------

US3312201

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 21:16:54

Generated On: 11 Aug 2021 22:16:12

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) _____

US3312201

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 21:16:54

Generated On: 11 Aug 2021 22:16:12

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.

US3312201

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 21:16:54

Generated On: 11 Aug 2021 22:16:12

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

10 MAR 2021

Collection time (00:00-23:59)

13:43 (24 HR)

Collection date and time (derived)

10 MAR 2021 13:43

US3312201

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:16:54

Generated On: 11 Aug 2021 22:16:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312201

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 20:40:11

Generated On: 11 Aug 2021 22:16:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312201

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 20:40:11

Generated On: 11 Aug 2021 22:16:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312201

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

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

US3312201

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3312201

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:16:12

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

US3312201

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:16:12

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3312201

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

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 21:16:13

Generated On: 11 Aug 2021 22:16:12

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

Visit date (dd MMM yyyy)	12 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
------------	---------------

US3312201

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

Form: Unblinding

Data signed: (b) (4) 09 Apr 2021 15:58:10

Generated On: 11 Aug 2021 22:16:12

Date of updated informed consent (<i>dd MMM yyyy</i>)	12 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>)	12 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

US3312201

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Apr 2021 21:16:13

Generated On: 11 Aug 2021 22:16:12

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

US3312201

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 21:16:13

Generated On: 11 Aug 2021 22:16:12

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)	12 JAN 2021
Time of assessment (00:00-23:59)	13:34 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 13:34
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	97 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	151 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG

US3312201

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 21:16:13

Generated On: 11 Aug 2021 22:16:12

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)	12 JAN 2021
Time of assessment (00:00-23:59)	15:13 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 15:13
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	159 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	99 mmHg
Diastolic Blood Pressure units	MMHG

US3312201

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

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 21:16:13

Generated On: 11 Aug 2021 22:16:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 JAN 2021

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

US3312201

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

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 21:16:13

Generated On: 11 Aug 2021 22:16:12

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) 12 JAN 2021

What was the treatment time? (00:00-23:59) 14:42 (24 HR)

Treatment Date and Time (derived) 12 JAN 2021 14:42

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

US3312201

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 21:16:13

Generated On: 11 Aug 2021 22:16:12

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 JAN 2021

Collection time (00:00-23:59)

13:09 (24 HR)

Collection date and time (derived)

12 JAN 2021 13:09

US3312201

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Apr 2021 21:16:13

Generated On: 11 Aug 2021 22:16:12

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00 - 23:59)	13:08
Collection Date and Time (derived)	12 JAN 2021 13:08

US3312201

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

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:16:13

Generated On: 11 Aug 2021 22:16:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312201

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:16:14

Generated On: 11 Aug 2021 22:16:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312201

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:16:14

Generated On: 11 Aug 2021 22:16:12

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

US3312201

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 21:16:13

Generated On: 11 Aug 2021 22:16:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 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

US3312201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 21:16:13

Generated On: 11 Aug 2021 22:16:12

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)	09 FEB 2021
Time of assessment (00:00-23:59)	13:07 (24 HR)
Vital Signs Date and Time (derived)	09 FEB 2021 13:07
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	99 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

US3312201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 21:16:13

Generated On: 11 Aug 2021 22:16:12

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)	09 FEB 2021
Time of assessment (00:00-23:59)	14:47 (24 HR)
Vital Signs Date and Time (derived)	09 FEB 2021 14:47
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	96 mmHg
Diastolic Blood Pressure units	MMHG

US3312201

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 21:16:13

Generated On: 11 Aug 2021 22:16:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 FEB 2021

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

US3312201

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 21:16:13

Generated On: 11 Aug 2021 22:16:12

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) 09 FEB 2021

What was the treatment time? (00:00-23:59) 14:16 (24 HR)

Treatment Date and Time (derived) 09 FEB 2021 14:16

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

US3312201

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:16:13

Generated On: 11 Aug 2021 22:16:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312201

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:16:13

Generated On: 11 Aug 2021 22:16:12

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

US3312201

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:16:13

Generated On: 11 Aug 2021 22:16:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312201

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 21:16:13

Generated On: 11 Aug 2021 22:16:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3312201

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 21:16:13

Generated On: 11 Aug 2021 22:16:12

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) _____

US3312201

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 21:16:13

Generated On: 11 Aug 2021 22:16:12

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.

US3312201

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 21:16:13

Generated On: 11 Aug 2021 22:16:12

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

Collection date (dd MMM yyyy)	10 MAR 2021
-------------------------------	-------------

Collection time (00:00-23:59)	13:43 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	10 MAR 2021 13:43
------------------------------------	-------------------

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 05 Apr 2021 21:16:14

Generated On: 11 Aug 2021 22:16:12

Visit Date	12 JAN 2021
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	True
Immunogenicity Assessment	False
Pregnancy Test	False

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 21:16:14

Generated On: 11 Aug 2021 22:16:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 JAN 2021
Time of assessment (<i>00:00-23:59</i>)	13:40 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 13:40
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	95 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 05 Apr 2021 21:16:14

Generated On: 11 Aug 2021 22:16:12

Visit Date	12 JAN 2021
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	True
Immunogenicity Assessment	False
Pregnancy Test	False

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 21:16:14

Generated On: 11 Aug 2021 22:16:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 JAN 2021
Time of assessment (<i>00:00-23:59</i>)	15:18 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 15:18
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	159 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	97 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312201

Folder: **Unscheduled 17 Sep 2020**

Form: **Unscheduled Visit Assessment**

Data signed: (b) (4) 05 Apr 2021 21:16:14

Generated On: 11 Aug 2021 22:16:12

Visit Date	17 SEP 2020
------------	-------------

Please check all assessments that apply for this visit

Physical Exam	False
---------------	-------

Vital Signs	True
-------------	------

Immunogenicity Assessment	False
---------------------------	-------

Pregnancy Test	False
----------------	-------

US3312201

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 21:16:14

Generated On: 11 Aug 2021 22:16:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	17 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	14:33 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 14:33
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	91 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312201

Folder: **Unscheduled 20 Aug 2020**

Form: **Unscheduled Visit Assessment**

Data signed: (b) (4) 05 Apr 2021 21:16:14

Generated On: 11 Aug 2021 22:16:12

Visit Date	20 AUG 2020
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	True
Immunogenicity Assessment	False
Pregnancy Test	False

US3312201

Folder: Unscheduled 20 Aug 2020

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 21:16:14

Generated On: 11 Aug 2021 22:16:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	20 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	17:00 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 17:00
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	93 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	97 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312201

Folder: Unscheduled 28 Oct 2020

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 05 Apr 2021 21:16:14

Generated On: 11 Aug 2021 22:16:12

Visit Date	28 OCT 2020
------------	-------------

Please check all assessments that apply for this visit

Physical Exam	False
---------------	-------

Vital Signs	True
-------------	------

Immunogenicity Assessment	False
---------------------------	-------

Pregnancy Test	False
----------------	-------

US3312201

Folder: Unscheduled 28 Oct 2020

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 21:16:14

Generated On: 11 Aug 2021 22:16:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	28 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	12:07 (24 HR)
Vital Signs Date and Time (derived)	28 OCT 2020 12:07
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	174 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	115 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312201

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 15:50:54

Generated On: 11 Aug 2021 22:16:12

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3312201

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 15:50:54

Generated On: 11 Aug 2021 22:16:12

AEID	
Adverse event	DIVERTICULITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	24 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	09 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

324 of 1916

US3312201

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 15:50:54

Generated On: 11 Aug 2021 22:16:12

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input checked="" type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

US3312201

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Mar 2021 15:50:54

Generated On: 11 Aug 2021 22:16:12

AEID

Adverse event

COLONIC POLYP

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

09 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

09 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

326 of 1916

EAB) (1725)

US3312201

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Mar 2021 15:50:54

Generated On: 11 Aug 2021 22:16:12

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3312201

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Mar 2021 15:50:54

Generated On: 11 Aug 2021 22:16:12

AEID

Adverse event

ELEVATED SYSTOLIC BLOOD
PRESSURE

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

28 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

28 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

328 of 1916

EAB) (1725)

US3312201

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Mar 2021 15:50:54

Generated On: 11 Aug 2021 22:16:12

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

US3312201

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 12 Mar 2021 15:50:54

Generated On: 11 Aug 2021 22:16:12

AEID

Adverse event

ELEVATED DIASTOLIC BLOOD
PRESSURE

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

28 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

28 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

330 of 1916

EAB) (1725)

US3312201

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 12 Mar 2021 15:50:54

Generated On: 11 Aug 2021 22:16:12

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

US3312201

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 12 Mar 2021 15:50:54

Generated On: 11 Aug 2021 22:16:12

AEID

Adverse event

ABRASION LEFT DELTOID

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

10 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

332 of 1916

EAB) (1725)

US3312201

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 12 Mar 2021 15:50:54

Generated On: 11 Aug 2021 22:16:12

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" 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)	_____

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Apr 2021 21:16:13

Generated On: 11 Aug 2021 22:16:12

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

Yes ☒

No ☐

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

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 06 Apr 2021 21:33:00

Generated On: 11 Aug 2021 22:16:12

Name of Medication HYDROCODONE

Prophylaxis Yes ☐
No ☒

Indication L2-L5 HERNIATED DISC

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

335 of 1916

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 06 Apr 2021 21:33:00

Generated On: 11 Aug 2021 22:16:12

	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 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 06 Apr 2021 21:33:00

Generated On: 11 Aug 2021 22:16:12

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication L2-L5 HERNIATED LUMBAR
DISC

Dose per administration 10

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)

337 of 1916

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 06 Apr 2021 21:33:00

Generated On: 11 Aug 2021 22:16:12

	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 MAR 2020	
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)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 06 Apr 2021 21:33:00

Generated On: 11 Aug 2021 22:16:12

Name of Medication CIPROFLOXACIN

Prophylaxis Yes ☐
No ☒

Indication DIVERTICULLITIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

339 of 1916

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 06 Apr 2021 21:33:00

Generated On: 11 Aug 2021 22:16:12

	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)	28 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 06 Apr 2021 21:33:00

Generated On: 11 Aug 2021 22:16:12

Name of Medication TRANSFORAMINAL EPIDURAL
STERIOD INJECTION

Prophylaxis Yes ☐
No ☒

Indication BACK PAIN

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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)

341 of 1916

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 06 Apr 2021 21:33:00

Generated On: 11 Aug 2021 22:16:12

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	INTRA-ARTICULAR	
Start date (dd MMM yyyy)	11 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	11 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3312201

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Apr 2021 21:16:13

Generated On: 11 Aug 2021 22:16:12

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3312201

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 05 Apr 2021 21:16:13

Generated On: 11 Aug 2021 22:16:12

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
9 OCT 2020	POLYPECTOMY	Adverse Event	

US3312201

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 05 Apr 2021 21:16:13

Generated On: 11 Aug 2021 22:16:12

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

Primary reason for dosing discontinuation

AE (specify) ☒

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3312201

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:16:12

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 ☐

Audit

US3312201 (Prod: Johnson County Clin-Trials)

US3312201

Form: Participant Creation

Generated On: 11 Aug 2021 22:16:12

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'US3312201'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	20 Aug 2020 19:49:25

US3312201

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:16:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 21:14:19

US3312201

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '20 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	20 Aug 2020 19:49:26

US3312201

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4)	20 Aug 2020 21:14:19

US3312201

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:16:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User entered 'SCRN'	System	20 Aug 2020 21:14:19

US3312201

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered (b) (6) 1954'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	20 Aug 2020 19:49:27

US3312201

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:16:12

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User closed query ' Per DMR: Since the Inclusion/exclusion Criteria Summary form has been updated, kindly consider to complete the demographics form . ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Aug 2020 19:24:53
Query ' Per DMR: Since the Inclusion/exclusion Criteria Summary form has been updated, kindly consider to complete the demographics form . ' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:34:25
User entered '65'	Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:34:21
User opened query ' Per DMR: Since the Inclusion/exclusion Criteria Summary form has been updated, kindly consider to complete the demographics form . ' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 06:34:44

US3312201

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:16:12

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User entered 'YEARS'	System	27 Aug 2020 16:34:21

US3312201

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:16:12

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User entered '65'	System	20 Aug 2020 21:14:33

US3312201

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:16:12

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Male (M)'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:34:21

US3312201

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:16:12

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:34:21

US3312201

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:16:12

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'I'	(b) (4) Karol Moore (b) (4)	27 Aug 2020 16:34:21

US3312201

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:16:12

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:34:21

US3312201

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:16:12

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:34:21

US3312201

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:16:12

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:34:21

US3312201

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:16:12

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '0'	(b) (4) Karol Moore (b) (4)	27 Aug 2020 16:34:21

US3312201

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:16:12

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:34:21

US3312201

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:16:12

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:34:21

US3312201

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:16:12

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:34:21

US3312201

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:16:12

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:34:21

US3312201

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:16:12

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '20 Aug 2020'	Christa Estrada (b) (4)	20 Aug 2020 21:14:33

US3312201

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User entered 'Aug 2020'	System	20 Aug 2020 21:14:33

US3312201

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User entered '2020'	System	20 Aug 2020 21:14:33

US3312201

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:16:12

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Amendment 2 (2)'	Christa Estrada (b) (4)	20 Aug 2020 21:14:33

US3312201

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 21:14:33

US3312201

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered empty.	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 21:14:33

US3312201

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:16:12

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered empty.	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 21:14:33

US3312201

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:16:12

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 21:14:33

US3312201

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:16:12

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	20 Aug 2020 19:49:26

US3312201

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:16:12

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User entered 'I'	System	20 Aug 2020 21:14:43

US3312201

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 21:14:43

US3312201

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:16:12

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	27 Aug 2020 16:34:32

US3312201

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:16:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Spinal fractures and dislocations, PT: Cervical vertebral fracture, LLT: Cervical vertebral fracture - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 09:02:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 09:02:41
Data point term sent to Coder	System	27 Aug 2020 16:35:45
User entered 'CERVICAL FRACTURE'	Karol Moore (b) (4)	27 Aug 2020 16:34:46

US3312201

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'UN UNK 2001'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:34:46

US3312201

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:16:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:34:46

US3312201

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:16:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	27 Aug 2020 16:35:23
User entered 'Yes (Y)'	Karol Moore (b) (4)	27 Aug 2020 16:34:46
	(b) (4)	

US3312201

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'UN UNK 2001' reason for change:	(b) (4)	
Data Entry Error	Karol Moore (b) (4)	27 Aug 2020 16:35:23
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	27 Aug 2020 16:34:46
	(b) (4)	

US3312201

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:16:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:34:46

US3312201

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User entered 'Jan 2001'	System	27 Aug 2020 16:34:46

US3312201

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User entered '2001'	System	27 Aug 2020 16:34:46

US3312201

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User entered 'Jan 2001'	System	27 Aug 2020 16:35:23
User entered empty.	System	27 Aug 2020 16:34:46

US3312201

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User entered '2001'	System	27 Aug 2020 16:35:23
User entered empty.	System	27 Aug 2020 16:34:46

US3312201

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:16:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal fusion surgery, LLT: Fusion cervical spine - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:37:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:37:00
Data point term sent to Coder	System	27 Aug 2020 16:35:45
User entered 'CERVICAL FUSION'	Karol Moore (b) (4)	27 Aug 2020 16:35:12

US3312201

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'UN UNK 2001'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:35:12

US3312201

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:16:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:35:12

US3312201

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:16:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	27 Aug 2020 16:35:12

US3312201

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'UN UNK 2001'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:35:12

US3312201

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:16:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:35:12

US3312201

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User entered 'Jan 2001'	System	27 Aug 2020 16:35:12

US3312201

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User entered '2001'	System	27 Aug 2020 16:35:12

US3312201

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User entered 'Jan 2001'	System	27 Aug 2020 16:35:12

US3312201

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User entered '2001'	System	27 Aug 2020 16:35:12

US3312201

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:16:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Lumbar disc herniation - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 10:01:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 10:01:35
Data point term sent to Coder	System	27 Aug 2020 16:36:47
User entered 'HERNIATED L2, L3, L4, L5 DISC'	Karol Moore (b) (4)	27 Aug 2020 16:35:47

US3312201

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'UN UNK 2010'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:35:47

US3312201

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:16:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:35:47

US3312201

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:16:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	27 Aug 2020 16:35:47

US3312201

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'UN UNK 2013'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:35:47

US3312201

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:16:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:35:47

US3312201

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User entered 'Jan 2010'	System	27 Aug 2020 16:35:47

US3312201

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User entered '2010'	System	27 Aug 2020 16:35:47

US3312201

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User entered 'Jan 2013'	System	27 Aug 2020 16:35:47

US3312201

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User entered '2013'	System	27 Aug 2020 16:35:47

US3312201

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:16:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal fusion surgery, LLT: Fusion lumbar spine - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 22:35:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 22:35:53
Data point term sent to Coder	System	27 Aug 2020 16:36:47
User entered 'LUMBAR FUSION L2-L5'	Karol Moore (b) (4)	27 Aug 2020 16:36:04

US3312201

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'UN UNK 2013'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:36:04

US3312201

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:16:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:36:04

US3312201

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:16:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	27 Aug 2020 16:36:04

US3312201

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'UN UNK 2013'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:36:04

US3312201

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:16:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:36:04

US3312201

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User entered 'Jan 2013'	System	27 Aug 2020 16:36:04

US3312201

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User entered '2013'	System	27 Aug 2020 16:36:04

US3312201

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User entered 'Jan 2013'	System	27 Aug 2020 16:36:04

US3312201

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User entered '2013'	System	27 Aug 2020 16:36:04

US3312201

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:16:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 21:03:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 21:03:49
Data point term sent to Coder	System	31 Aug 2020 21:02:21
User entered 'BACK PAIN'	Monica Atwood (b) (4)	31 Aug 2020 21:02:06

US3312201

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'UN UNK 2010'	(b) (4) Monica Atwood (b) (4)	31 Aug 2020 21:02:06

US3312201

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:16:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '0'	(b) (4) Monica Atwood (b) (4)	31 Aug 2020 21:02:06

US3312201

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:16:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4)	31 Aug 2020 21:02:06

US3312201

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered empty.	(b) (4) Monica Atwood (b) (4)	31 Aug 2020 21:02:06

US3312201

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:16:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '0'	(b) (4) Monica Atwood (b) (4)	31 Aug 2020 21:02:06

US3312201

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User entered 'Jan 2010'	System	31 Aug 2020 21:02:06

US3312201

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User entered '2010'	System	31 Aug 2020 21:02:06

US3312201

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User entered empty.	System	31 Aug 2020 21:02:06

US3312201

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User entered empty.	System	31 Aug 2020 21:02:06

US3312201

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:16:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain, LLT: Abdominal pain - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 21:26:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 21:26:51
Data point term sent to Coder	System	02 Nov 2020 16:16:46
User entered 'INTERMITTENT ABDOMINAL PAIN'	Monica Atwood (b) (4)	02 Nov 2020 16:16:36

US3312201

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'UN May 2020'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:16:36

US3312201

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:16:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '0'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:16:36

US3312201

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:16:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:16:36

US3312201

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered empty.	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:16:36

US3312201

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:16:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '0'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:16:36

US3312201

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User entered 'May 2020'	System	02 Nov 2020 16:16:36

US3312201

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User entered '2020'	System	02 Nov 2020 16:16:36

US3312201

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User entered empty.	System	02 Nov 2020 16:16:36

US3312201

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User entered empty.	System	02 Nov 2020 16:16:36

US3312201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	27 Aug 2020 16:36:33

US3312201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '20 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:36:33

US3312201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '15:09'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:36:33

US3312201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User entered '20 Aug 2020 15:09'	System	27 Aug 2020 16:36:33

US3312201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '72' in	(b) (4)	27 Aug 2020 16:36:33
DataPoint set to visible.	Karol Moore (b) (4)	20 Aug 2020 21:14:43
	(b) (4)	
	System	

US3312201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '226' lb	(b) (4) Karol Moore (b) (4)	27 Aug 2020 16:36:33
DataPoint set to visible.	(b) (4) System	20 Aug 2020 21:14:43

US3312201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
Amendment Manager: User entered '30.71520'	System	17 Sep 2020 00:16:57
User entered '30.7'	System	27 Aug 2020 16:36:33
DataPoint set to visible.	System	20 Aug 2020 21:14:43

US3312201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User entered 'kg/m2'	System	27 Aug 2020 16:36:33
DataPoint set to visible.	System	20 Aug 2020 21:14:43

US3312201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:36:33

US3312201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:36:33

US3312201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:36:33

US3312201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	27 Aug 2020 16:36:33

US3312201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User entered 'bpm'	System	27 Aug 2020 16:36:33

US3312201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	27 Aug 2020 16:36:33

US3312201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User entered 'breaths/min'	System	27 Aug 2020 16:36:33

US3312201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	27 Aug 2020 16:36:33

US3312201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User entered 'mmHg'	System	27 Aug 2020 16:36:33

US3312201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	27 Aug 2020 16:36:33

US3312201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User entered 'mmHg'	System	27 Aug 2020 16:36:33

US3312201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16

US3312201

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16

US3312201

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:16:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:36:40

US3312201

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:16:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '20 Aug 2020'	(b) (4) Karol Moore (b) (4)	27 Aug 2020 16:36:40
	(b) (4)	

US3312201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	27 Aug 2020 16:37:08

US3312201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:37:08

US3312201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:37:08

US3312201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:37:08

US3312201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	27 Aug 2020 16:37:08

US3312201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	27 Aug 2020 16:37:08

US3312201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:37:08

US3312201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:37:08

US3312201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:37:08

US3312201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	27 Aug 2020 16:37:08

US3312201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	27 Aug 2020 16:37:08

US3312201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:12

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:37:08

US3312201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:12

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered empty.	(b) (4) Karol Moore (b) (4)	27 Aug 2020 16:37:08

US3312201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:12

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:37:08

US3312201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '0'	(b) (4) Karol Moore (b) (4)	27 Aug 2020 16:37:08

US3312201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '0'	Karol Moore (b) (4)	27 Aug 2020 16:37:08

US3312201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '0'	(b) (4) Karol Moore (b) (4)	27 Aug 2020 16:37:08

US3312201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:37:08

US3312201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '0'	(b) (4) Karol Moore (b) (4)	27 Aug 2020 16:37:08

US3312201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:12

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:37:08

US3312201

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:12

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:56:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'RESIDES IN COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:37:08

US3312201

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:16:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 21:14:54

US3312201

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '20 Aug 2020'	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 21:14:54

US3312201

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4)	20 Aug 2020 21:14:54

US3312201

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:16:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User entered 'VISIT1'	System	20 Aug 2020 21:14:54

US3312201

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '20 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	20 Aug 2020 20:49:37

US3312201

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 06:01:19
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 06:01:19
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Aug 2020 20:49:37
User entered '187335' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	20 Aug 2020 20:49:37

US3312201

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	20 Aug 2020 20:49:37

US3312201

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:16:12

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)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'No (N)'	Christa Estrada (b) (4)	20 Aug 2020 21:15:05

US3312201

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:16:12

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)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'No (N)'	Christa Estrada (b) (4)	20 Aug 2020 21:15:05

US3312201

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 21:15:05

US3312201

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 21:15:05

US3312201

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:16:12

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 21:15:05

US3312201

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'No (N)'	(b) (4) Heather Barker (b) (4)	30 Oct 2020 17:59:19
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 10:37:28
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:50:54

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:16:12

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:38:11

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:16:12

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:38:11

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:16:12

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	27 Aug 2020 16:38:11

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:16:12

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	27 Aug 2020 16:38:11
	(b) (4)	

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4)	27 Aug 2020 16:38:11
	(b) (4)	

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:38:11

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '20 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:38:11

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '15:09'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:38:11

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User entered '20 Aug 2020 15:09'	System	27 Aug 2020 16:38:11

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '98' F	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:38:11

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:38:11

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:38:11

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '87'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:38:11

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User entered 'bpm'	System	27 Aug 2020 16:38:11

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '12'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:38:11

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User entered 'breaths/min'	System	27 Aug 2020 16:38:11

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '129'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:38:11

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User entered 'mmHg'	System	27 Aug 2020 16:38:11

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '82'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:38:11

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User entered 'mmHg'	System	27 Aug 2020 16:38:11

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:16:12

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	27 Aug 2020 16:38:11

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:16:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:38:11

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:38:11

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:38:11

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '20 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:38:11

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '16:42'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:38:11

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User entered '20 Aug 2020 16:42'	System	27 Aug 2020 16:38:11

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '97.9' F	(b) (4) Karol Moore (b) (4)	27 Aug 2020 16:38:11

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:38:11

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:38:11

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '93'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:38:11

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User entered 'bpm'	System	27 Aug 2020 16:38:11

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '16'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:38:11

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User entered 'breaths/min'	System	27 Aug 2020 16:38:11

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '148'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:38:11

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User entered 'mmHg'	System	27 Aug 2020 16:38:11

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	31 Aug 2020 17:41:53
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'CORRECT AS ENTERED. NCS. SEE UNSCHEDULED REPEAT VITALS' (Site from System).	Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:38:44
User opened query 'Diastolic Blood Pressure reportedSystem is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		27 Aug 2020 16:38:11
User entered '101'	Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:38:11

US3312201

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User entered 'mmHg'	System	27 Aug 2020 16:38:11

US3312201

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:16:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'No (N)'	(b) (4)	27 Aug 2020 16:38:50
	Karol Moore (b) (4)	
	(b) (4)	

US3312201

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:16:12

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:38:50

US3312201

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 21:15:38

US3312201

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered empty.	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 21:15:38

US3312201

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

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)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered empty.	Christa Estrada (b) (4)	20 Aug 2020 21:15:38

US3312201

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User entered 'MRNA-1273 OR PLACEBO'	System	20 Aug 2020 21:15:38

US3312201

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '20 Aug 2020'	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 21:15:38

US3312201

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '16:06'	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 21:15:38

US3312201

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User entered '20 Aug 2020 16:06'	System	20 Aug 2020 21:15:38

US3312201

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Left Arm (LEFT ARM)'	Christa Estrada (b) (4)	20 Aug 2020 21:15:38

US3312201

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User entered 'ONCE'	System	20 Aug 2020 21:15:38

US3312201

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User entered 'INTRAMUSCULAR'	System	20 Aug 2020 21:15:38

US3312201

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:39:04

US3312201

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '20 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:39:04

US3312201

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '15:37'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:39:04

US3312201

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User entered '20 Aug 2020 15:37'	System	27 Aug 2020 16:39:04

US3312201

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:16:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '20 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:39:15

US3312201

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:16:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:39:15

US3312201

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:16:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:39:15

US3312201

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:16:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '15:30'	(b) (4)	27 Aug 2020 16:39:15
	Karol Moore (b) (4)	
	(b) (4)	

US3312201

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User entered '20 Aug 2020 15:30'	System	27 Aug 2020 16:39:15

US3312201

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:16:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:39:15

US3312201

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:16:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:39:15

US3312201

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:16:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:39:15

US3312201

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User entered empty.	System	27 Aug 2020 16:39:15

US3312201

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	27 Aug 2020 16:39:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 16:39:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Karol Moore (b) (4)	27 Aug 2020 16:39:26
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	27 Aug 2020 16:39:22
User entered empty.	System	27 Aug 2020 16:39:22
	Karol Moore (b) (4)	27 Aug 2020 16:39:22
	(b) (4)	

US3312201

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User entered '1'	System	27 Aug 2020 16:39:26
User entered empty.	System	27 Aug 2020 16:39:22

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
Data entry locked.	System	20 Aug 2020 21:15:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:16:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-20T16:44:04', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'c0e3bb40-cc0b-4c1f-a39d-bdb5758b98a0'	System	20 Aug 2020 21:45:15
User entered 'Yes (Y)'	System	20 Aug 2020 21:45:15

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:16:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-20T16:44:15', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'c0e3bb40-cc0b-4c1f-a39d-bdb5758b98a0'	System	20 Aug 2020 21:45:15
User entered '97.9'	System	20 Aug 2020 21:45:15

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-20T16:45:03', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'c0e3bb40-cc0b-4c1f-a39d-bdb5758b98a0'	System	20 Aug 2020 21:45:15
User entered 'No (N)'	System	20 Aug 2020 21:45:15

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:16:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-20T16:45:11', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'c0e3bb40-cc0b-4c1f-a39d-bdb5758b98a0'	System	20 Aug 2020 21:45:15
User entered '20 Aug 2020 16:45'	System	20 Aug 2020 21:45:15

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:16:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '20 Aug 2020 16:26'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:16:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '20 Aug 2020 18:56'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
Data entry locked.	System	20 Aug 2020 21:15:38
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:16:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-20T22:32:34', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '48b6ea44-1aa8-4aa2-aea8-543c5c65e625'	System	21 Aug 2020 03:33:08
User entered 'Yes (Y)'	System	21 Aug 2020 03:33:08

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:16:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-20T22:32:45', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '48b6ea44-1aa8-4aa2-aea8-543c5c65e625'	System	21 Aug 2020 03:33:08
User entered '98.2'	System	21 Aug 2020 03:33:08

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-20T22:32:52', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '48b6ea44-1aa8-4aa2-aea8-543c5c65e625'	System	21 Aug 2020 03:33:08
User entered 'No (N)'	System	21 Aug 2020 03:33:08

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:16:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-20T22:33:05', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '48b6ea44-1aa8-4aa2-aea8-543c5c65e625'	System	21 Aug 2020 03:33:08
User entered '20 Aug 2020 22:33'	System	21 Aug 2020 03:33:08

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:16:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '20 Aug 2020 19:51'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:16:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
Data entry locked.	System	20 Aug 2020 21:15:38
User entered 'Day 2'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:16:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-21T23:19:16', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'df3bc2e6-523c-4fb5-8817-ed37d9dbad02'	System	22 Aug 2020 04:19:48
User entered 'Yes (Y)'	System	22 Aug 2020 04:19:48

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:16:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-21T23:19:26', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'df3bc2e6-523c-4fb5-8817-ed37d9dbad02'	System	22 Aug 2020 04:19:48
User entered '97.0'	System	22 Aug 2020 04:19:48

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-21T23:19:31', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'df3bc2e6-523c-4fb5-8817-ed37d9dbad02'	System	22 Aug 2020 04:19:48
User entered 'No (N)'	System	22 Aug 2020 04:19:48

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:16:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-21T23:19:43', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'df3bc2e6-523c-4fb5-8817-ed37d9dbad02'	System	22 Aug 2020 04:19:48
User entered '21 Aug 2020 23:19'	System	22 Aug 2020 04:19:48

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:16:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:16:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
Data entry locked.	System	20 Aug 2020 21:15:38
User entered 'Day 3'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:16:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-22T20:49:38', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'cf2000af-06ed-4894-9bd0-02292326d4b0'	System	23 Aug 2020 01:50:06
User entered 'Yes (Y)'	System	23 Aug 2020 01:50:06

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:16:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-22T20:49:48', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'cf2000af-06ed-4894-9bd0-02292326d4b0'	System	23 Aug 2020 01:50:06
User entered '97.5'	System	23 Aug 2020 01:50:06

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-22T20:49:52', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'cf2000af-06ed-4894-9bd0-02292326d4b0'	System	23 Aug 2020 01:50:06
User entered 'No (N)'	System	23 Aug 2020 01:50:06

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:16:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-22T20:50:00', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'cf2000af-06ed-4894-9bd0-02292326d4b0'	System	23 Aug 2020 01:50:06
User entered '22 Aug 2020 20:50'	System	23 Aug 2020 01:50:06

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:16:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:16:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
Data entry locked.	System	20 Aug 2020 21:15:38
User entered 'Day 4'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:16:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-23T21:18:38', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '393d23e0-fc63-4e93-96df-400d12a343e3'	System	24 Aug 2020 02:19:01
User entered 'Yes (Y)'	System	24 Aug 2020 02:19:01

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:16:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-23T21:18:48', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '393d23e0-fc63-4e93-96df-400d12a343e3'	System	24 Aug 2020 02:19:01
User entered '98.4'	System	24 Aug 2020 02:19:01

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-23T21:18:52', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '393d23e0-fc63-4e93-96df-400d12a343e3'	System	24 Aug 2020 02:19:01
User entered 'No (N)'	System	24 Aug 2020 02:19:01

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:16:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-23T21:18:58', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '393d23e0-fc63-4e93-96df-400d12a343e3'	System	24 Aug 2020 02:19:01
User entered '23 Aug 2020 21:18'	System	24 Aug 2020 02:19:01

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:16:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:16:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
Data entry locked.	System	20 Aug 2020 21:15:38
User entered 'Day 5'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:16:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-24T21:15:40', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '3f413a84-5412-49f0-8c2b-470558c7ced4'	System	25 Aug 2020 02:16:07
User entered 'Yes (Y)'	System	25 Aug 2020 02:16:07

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:16:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-24T21:15:48', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '3f413a84-5412-49f0-8c2b-470558c7ced4'	System	25 Aug 2020 02:16:07
User entered '97.8'	System	25 Aug 2020 02:16:07

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-24T21:15:52', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '3f413a84-5412-49f0-8c2b-470558c7ced4'	System	25 Aug 2020 02:16:07
User entered 'No (N)'	System	25 Aug 2020 02:16:07

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:16:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-24T21:15:59', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '3f413a84-5412-49f0-8c2b-470558c7ced4'	System	25 Aug 2020 02:16:07
User entered '24 Aug 2020 21:15'	System	25 Aug 2020 02:16:07

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:16:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:16:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
Data entry locked.	System	20 Aug 2020 21:15:38
User entered 'Day 6'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:16:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-26T00:10:26', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '2124ca91-4481-40a2-9fc3-87e111b286cc'	System	26 Aug 2020 05:10:44
User entered 'Yes (Y)'	System	26 Aug 2020 05:10:44

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:16:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-26T00:10:31', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '2124ca91-4481-40a2-9fc3-87e111b286cc'	System	26 Aug 2020 05:10:44
User entered '99.3'	System	26 Aug 2020 05:10:44

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-26T00:10:34', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '2124ca91-4481-40a2-9fc3-87e111b286cc'	System	26 Aug 2020 05:10:44
User entered 'No (N)'	System	26 Aug 2020 05:10:44

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:16:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-26T00:10:41', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '2124ca91-4481-40a2-9fc3-87e111b286cc'	System	26 Aug 2020 05:10:44
User entered '26 Aug 2020 00:10'	System	26 Aug 2020 05:10:44

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:16:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:16:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
Data entry locked.	System	20 Aug 2020 21:15:38
User entered 'Day 7'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:16:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-27T00:01:17', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '5b134f78-4855-4f32-9356-c9505482e3ed'	System	27 Aug 2020 05:02:03
User entered 'Yes (Y)'	System	27 Aug 2020 05:02:03

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:16:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-27T00:01:50', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '5b134f78-4855-4f32-9356-c9505482e3ed'	System	27 Aug 2020 05:02:03
User entered '97.7'	System	27 Aug 2020 05:02:03

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-27T00:01:53', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '5b134f78-4855-4f32-9356-c9505482e3ed'	System	27 Aug 2020 05:02:03
User entered 'No (N)'	System	27 Aug 2020 05:02:03

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:16:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-27T00:01:58', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '5b134f78-4855-4f32-9356-c9505482e3ed'	System	27 Aug 2020 05:02:03
User entered '27 Aug 2020 00:01'	System	27 Aug 2020 05:02:03

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:16:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:16:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
Data entry locked.	System	20 Aug 2020 21:15:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:16:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-20T16:45:33', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '8a5bf213-e331-415f-9098-31c4b6542326'	System	20 Aug 2020 21:46:06
User entered 'None (1)'	System	20 Aug 2020 21:46:06

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:16:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-20T16:45:37', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '8a5bf213-e331-415f-9098-31c4b6542326'	System	20 Aug 2020 21:46:06
User entered 'No (N)'	System	20 Aug 2020 21:46:06

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-20T16:45:42', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '8a5bf213-e331-415f-9098-31c4b6542326'	System	20 Aug 2020 21:46:06
User entered 'No (N)'	System	20 Aug 2020 21:46:06

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:16:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-20T16:45:52', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '8a5bf213-e331-415f-9098-31c4b6542326'	System	20 Aug 2020 21:46:06
User entered 'None (1)'	System	20 Aug 2020 21:46:06

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:16:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-20T16:46:03', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '8a5bf213-e331-415f-9098-31c4b6542326'	System	20 Aug 2020 21:46:06
User entered '20 Aug 2020 16:46'	System	20 Aug 2020 21:46:06

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:16:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '20 Aug 2020 16:26'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:16:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '20 Aug 2020 18:56'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
Data entry locked.	System	20 Aug 2020 21:15:38
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:16:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-20T22:35:01', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'b0db2609-95bf-4f62-887c-127ff274b4e0'	System	21 Aug 2020 03:35:23
User entered 'None (1)'	System	21 Aug 2020 03:35:23

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-20T22:35:04', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'b0db2609-95bf-4f62-887c-127ff274b4e0'	System	21 Aug 2020 03:35:23
User entered 'No (N)'	System	21 Aug 2020 03:35:23

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-20T22:35:07', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'b0db2609-95bf-4f62-887c-127ff274b4e0'	System	21 Aug 2020 03:35:23
User entered 'No (N)'	System	21 Aug 2020 03:35:23

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:16:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-20T22:35:11', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'b0db2609-95bf-4f62-887c-127ff274b4e0'	System	21 Aug 2020 03:35:23
User entered 'None (1)'	System	21 Aug 2020 03:35:23

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:16:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-20T22:35:21', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'b0db2609-95bf-4f62-887c-127ff274b4e0'	System	21 Aug 2020 03:35:23
User entered '20 Aug 2020 22:35'	System	21 Aug 2020 03:35:23

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:16:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '20 Aug 2020 19:51'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:16:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
Data entry locked.	System	20 Aug 2020 21:15:38
User entered 'Day 2'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:16:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-21T23:19:51', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'fa615aca-cfe8-4372-b2cd-b69b92145fad'	System	22 Aug 2020 04:20:16
User entered 'None (1)'	System	22 Aug 2020 04:20:16

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:16:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-21T23:19:54', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'fa615aca-cfe8-4372-b2cd-b69b92145fad'	System	22 Aug 2020 04:20:16
User entered 'No (N)'	System	22 Aug 2020 04:20:16

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-21T23:19:58', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'fa615aca-cfe8-4372-b2cd-b69b92145fad'	System	22 Aug 2020 04:20:16
User entered 'No (N)'	System	22 Aug 2020 04:20:16

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:16:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-21T23:20:03', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'fa615aca-cfe8-4372-b2cd-b69b92145fad'	System	22 Aug 2020 04:20:16
User entered 'None (1)'	System	22 Aug 2020 04:20:16

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:16:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-21T23:20:13', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'fa615aca-cfe8-4372-b2cd-b69b92145fad'	System	22 Aug 2020 04:20:16
User entered '21 Aug 2020 23:20'	System	22 Aug 2020 04:20:16

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:16:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:16:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
Data entry locked.	System	20 Aug 2020 21:15:38
User entered 'Day 3'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:16:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-22T20:50:07', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '703afaab-4505-45ae-a6c5-d1f22924bc72'	System	23 Aug 2020 01:50:44
User entered 'None (1)'	System	23 Aug 2020 01:50:44

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:16:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-22T20:50:11', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '703afaab-4505-45ae-a6c5-d1f22924bc72'	System	23 Aug 2020 01:50:44
User entered 'No (N)'	System	23 Aug 2020 01:50:44

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-22T20:50:17', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '703afaab-4505-45ae-a6c5-d1f22924bc72'	System	23 Aug 2020 01:50:44
User entered 'No (N)'	System	23 Aug 2020 01:50:44

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:16:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-22T20:50:29', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '703afaab-4505-45ae-a6c5-d1f22924bc72'	System	23 Aug 2020 01:50:44
User entered 'None (1)'	System	23 Aug 2020 01:50:44

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:16:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-22T20:50:40', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '703afaab-4505-45ae-a6c5-d1f22924bc72'	System	23 Aug 2020 01:50:44
User entered '22 Aug 2020 20:50'	System	23 Aug 2020 01:50:44

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:16:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:16:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
Data entry locked.	System	20 Aug 2020 21:15:38
User entered 'Day 4'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:16:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-23T21:19:37', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'ef5ca3da-e8c9-4473-ba75-e97bca4c884d'	System	24 Aug 2020 02:19:48
User entered 'None (1)'	System	24 Aug 2020 02:19:48

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:16:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-23T21:19:18', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'ef5ca3da-e8c9-4473-ba75-e97bca4c884d'	System	24 Aug 2020 02:19:48
User entered 'No (N)'	System	24 Aug 2020 02:19:48

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-23T21:19:22', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'ef5ca3da-e8c9-4473-ba75-e97bca4c884d'	System	24 Aug 2020 02:19:48
User entered 'No (N)'	System	24 Aug 2020 02:19:48

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:16:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-23T21:19:29', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'ef5ca3da-e8c9-4473-ba75-e97bca4c884d'	System	24 Aug 2020 02:19:48
User entered 'None (1)'	System	24 Aug 2020 02:19:48

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:16:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-23T21:19:45', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'ef5ca3da-e8c9-4473-ba75-e97bca4c884d'	System	24 Aug 2020 02:19:48
User entered '23 Aug 2020 21:19'	System	24 Aug 2020 02:19:48

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:16:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:16:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
Data entry locked.	System	20 Aug 2020 21:15:38
User entered 'Day 5'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:16:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-24T21:16:04', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'c34b95f9-4a82-47d2-9b5e-a0291ae9e774'	System	25 Aug 2020 02:16:32
User entered 'None (1)'	System	25 Aug 2020 02:16:32

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-24T21:16:08', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'c34b95f9-4a82-47d2-9b5e-a0291ae9e774'	System	25 Aug 2020 02:16:32
User entered 'No (N)'	System	25 Aug 2020 02:16:32

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-24T21:16:13', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'c34b95f9-4a82-47d2-9b5e-a0291ae9e774'	System	25 Aug 2020 02:16:32
User entered 'No (N)'	System	25 Aug 2020 02:16:32

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:16:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-24T21:16:19', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'c34b95f9-4a82-47d2-9b5e-a0291ae9e774'	System	25 Aug 2020 02:16:32
User entered 'None (1)'	System	25 Aug 2020 02:16:32

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:16:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-24T21:16:27', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'c34b95f9-4a82-47d2-9b5e-a0291ae9e774'	System	25 Aug 2020 02:16:32
User entered '24 Aug 2020 21:16'	System	25 Aug 2020 02:16:32

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:16:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:16:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
Data entry locked.	System	20 Aug 2020 21:15:38
User entered 'Day 6'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:16:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-26T00:10:49', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'ac3fc53b-7edb-4014-bd87-4e7fadc41ee9'	System	26 Aug 2020 05:11:17
User entered 'None (1)'	System	26 Aug 2020 05:11:17

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-26T00:11:00', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'ac3fc53b-7edb-4014-bd87-4e7fadc41ee9'	System	26 Aug 2020 05:11:17
User entered 'No (N)'	System	26 Aug 2020 05:11:17

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-26T00:11:06', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'ac3fc53b-7edb-4014-bd87-4e7fadc41ee9'	System	26 Aug 2020 05:11:17
User entered 'No (N)'	System	26 Aug 2020 05:11:17

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:16:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-26T00:11:09', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'ac3fc53b-7edb-4014-bd87-4e7fadc41ee9'	System	26 Aug 2020 05:11:17
User entered 'None (1)'	System	26 Aug 2020 05:11:17

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:16:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-26T00:11:14', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'ac3fc53b-7edb-4014-bd87-4e7fadc41ee9'	System	26 Aug 2020 05:11:17
User entered '26 Aug 2020 00:11'	System	26 Aug 2020 05:11:17

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:16:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:16:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
Data entry locked.	System	20 Aug 2020 21:15:38
User entered 'Day 7'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:16:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-27T00:02:03', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'b5a23ebc-d0a1-42e3-a8d6-faf2386a3a49'	System	27 Aug 2020 05:02:27
User entered 'None (1)'	System	27 Aug 2020 05:02:27

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:16:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-27T00:02:07', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'b5a23ebc-d0a1-42e3-a8d6-faf2386a3a49'	System	27 Aug 2020 05:02:27
User entered 'No (N)'	System	27 Aug 2020 05:02:27

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-27T00:02:11', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'b5a23ebc-d0a1-42e3-a8d6-faf2386a3a49'	System	27 Aug 2020 05:02:27
User entered 'No (N)'	System	27 Aug 2020 05:02:27

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:16:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-27T00:02:19', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'b5a23ebc-d0a1-42e3-a8d6-faf2386a3a49'	System	27 Aug 2020 05:02:27
User entered 'None (1)'	System	27 Aug 2020 05:02:27

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:16:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-27T00:02:24', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'b5a23ebc-d0a1-42e3-a8d6-faf2386a3a49'	System	27 Aug 2020 05:02:27
User entered '27 Aug 2020 00:02'	System	27 Aug 2020 05:02:27

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:16:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:16:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
Data entry locked.	System	20 Aug 2020 21:15:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:16:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-20T16:46:22', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '3f39b061-74ec-4984-b004-654cec7f1f1d'	System	20 Aug 2020 21:46:59
User entered 'None (0)'	System	20 Aug 2020 21:46:59

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:16:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-20T16:46:27', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '3f39b061-74ec-4984-b004-654cec7f1f1d'	System	20 Aug 2020 21:46:59
User entered 'None (0)'	System	20 Aug 2020 21:46:59

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:16:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-20T16:46:30', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '3f39b061-74ec-4984-b004-654cec7f1f1d'	System	20 Aug 2020 21:46:59
User entered 'None (0)'	System	20 Aug 2020 21:46:59

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:16:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-20T16:46:34', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '3f39b061-74ec-4984-b004-654cec7f1f1d'	System	20 Aug 2020 21:46:59
User entered 'None (0)'	System	20 Aug 2020 21:46:59

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:16:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-20T16:46:37', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '3f39b061-74ec-4984-b004-654cec7f1f1d'	System	20 Aug 2020 21:46:59
User entered 'None (0)'	System	20 Aug 2020 21:46:59

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:16:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-20T16:46:40', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '3f39b061-74ec-4984-b004-654cec7f1f1d'	System	20 Aug 2020 21:46:59
User entered 'None (0)'	System	20 Aug 2020 21:46:59

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:16:12

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)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-20T16:46:47', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '3f39b061-74ec-4984-b004-654cec7f1f1d'	System	20 Aug 2020 21:46:59
User entered 'No (N)'	System	20 Aug 2020 21:46:59

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:16:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-20T16:46:56', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '3f39b061-74ec-4984-b004-654cec7f1f1d'	System	20 Aug 2020 21:46:59
User entered '20 Aug 2020 16:46'	System	20 Aug 2020 21:46:59

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:16:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '20 Aug 2020 16:26'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:16:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '20 Aug 2020 18:56'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
Data entry locked.	System	20 Aug 2020 21:15:38
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:16:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-20T22:34:30', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'cc4dfa2a-651c-4e0f-a27c-d1a84acdf4a4'	System	21 Aug 2020 03:34:47
User entered 'None (0)'	System	21 Aug 2020 03:34:47

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:16:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-20T22:33:55', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'cc4dfa2a-651c-4e0f-a27c-d1a84acdf4a4'	System	21 Aug 2020 03:34:47
User entered 'None (0)'	System	21 Aug 2020 03:34:47

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:16:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-20T22:34:01', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'cc4dfa2a-651c-4e0f-a27c-d1a84acdf4a4'	System	21 Aug 2020 03:34:47
User entered 'None (0)'	System	21 Aug 2020 03:34:47

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:16:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-20T22:34:06', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'cc4dfa2a-651c-4e0f-a27c-d1a84acdf4a4'	System	21 Aug 2020 03:34:47
User entered 'None (0)'	System	21 Aug 2020 03:34:47

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:16:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-20T22:34:09', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'cc4dfa2a-651c-4e0f-a27c-d1a84acdf4a4'	System	21 Aug 2020 03:34:47
User entered 'None (0)'	System	21 Aug 2020 03:34:47

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:16:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-20T22:34:12', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'cc4dfa2a-651c-4e0f-a27c-d1a84acdf4a4'	System	21 Aug 2020 03:34:47
User entered 'None (0)'	System	21 Aug 2020 03:34:47

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:16:12

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)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-20T22:34:16', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'cc4dfa2a-651c-4e0f-a27c-d1a84acdf4a4'	System	21 Aug 2020 03:34:47
User entered 'No (N)'	System	21 Aug 2020 03:34:47

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:16:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-20T22:34:43', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'cc4dfa2a-651c-4e0f-a27c-d1a84acdf4a4'	System	21 Aug 2020 03:34:47
User entered '20 Aug 2020 22:34'	System	21 Aug 2020 03:34:47

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:16:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '20 Aug 2020 19:51'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:16:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
Data entry locked.	System	20 Aug 2020 21:15:38
User entered 'Day 2'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:16:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-21T23:20:19', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '982d6e7d-48ce-4c3f-b329-e7c4516e40fa'	System	22 Aug 2020 04:21:01
User entered 'None (0)'	System	22 Aug 2020 04:21:01

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:16:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-21T23:20:24', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '982d6e7d-48ce-4c3f-b329-e7c4516e40fa'	System	22 Aug 2020 04:21:01
User entered 'None (0)'	System	22 Aug 2020 04:21:01

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:16:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-21T23:20:27', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '982d6e7d-48ce-4c3f-b329-e7c4516e40fa'	System	22 Aug 2020 04:21:01
User entered 'None (0)'	System	22 Aug 2020 04:21:01

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:16:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-21T23:20:31', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '982d6e7d-48ce-4c3f-b329-e7c4516e40fa'	System	22 Aug 2020 04:21:01
User entered 'None (0)'	System	22 Aug 2020 04:21:01

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:16:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-21T23:20:35', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '982d6e7d-48ce-4c3f-b329-e7c4516e40fa'	System	22 Aug 2020 04:21:01
User entered 'None (0)'	System	22 Aug 2020 04:21:01

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:16:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-21T23:20:40', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '982d6e7d-48ce-4c3f-b329-e7c4516e40fa'	System	22 Aug 2020 04:21:01
User entered 'None (0)'	System	22 Aug 2020 04:21:01

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:16:12

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)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-21T23:20:49', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '982d6e7d-48ce-4c3f-b329-e7c4516e40fa'	System	22 Aug 2020 04:21:01
User entered 'No (N)'	System	22 Aug 2020 04:21:01

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:16:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-21T23:20:59', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '982d6e7d-48ce-4c3f-b329-e7c4516e40fa'	System	22 Aug 2020 04:21:01
User entered '21 Aug 2020 23:20'	System	22 Aug 2020 04:21:01

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:16:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:16:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
Data entry locked.	System	20 Aug 2020 21:15:38
User entered 'Day 3'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:16:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-22T20:50:46', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '260f71d6-891e-4e51-87c7-208f3804e594'	System	23 Aug 2020 01:51:18
User entered 'None (0)'	System	23 Aug 2020 01:51:18

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:16:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-22T20:50:49', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '260f71d6-891e-4e51-87c7-208f3804e594'	System	23 Aug 2020 01:51:18
User entered 'None (0)'	System	23 Aug 2020 01:51:18

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:16:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-22T20:50:52', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '260f71d6-891e-4e51-87c7-208f3804e594'	System	23 Aug 2020 01:51:18
User entered 'None (0)'	System	23 Aug 2020 01:51:18

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:16:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-22T20:50:55', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '260f71d6-891e-4e51-87c7-208f3804e594'	System	23 Aug 2020 01:51:18
User entered 'None (0)'	System	23 Aug 2020 01:51:18

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:16:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-22T20:50:59', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '260f71d6-891e-4e51-87c7-208f3804e594'	System	23 Aug 2020 01:51:18
User entered 'None (0)'	System	23 Aug 2020 01:51:18

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:16:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-22T20:51:02', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '260f71d6-891e-4e51-87c7-208f3804e594'	System	23 Aug 2020 01:51:18
User entered 'None (0)'	System	23 Aug 2020 01:51:18

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:16:12

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)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-22T20:51:05', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '260f71d6-891e-4e51-87c7-208f3804e594'	System	23 Aug 2020 01:51:18
User entered 'No (N)'	System	23 Aug 2020 01:51:18

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:16:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-22T20:51:16', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '260f71d6-891e-4e51-87c7-208f3804e594'	System	23 Aug 2020 01:51:18
User entered '22 Aug 2020 20:51'	System	23 Aug 2020 01:51:18

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:16:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:16:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
Data entry locked.	System	20 Aug 2020 21:15:38
User entered 'Day 4'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:16:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-23T21:19:49', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'b43326a5-bc74-439e-8671-c41b8e20d5f8'	System	24 Aug 2020 02:20:17
User entered 'None (0)'	System	24 Aug 2020 02:20:17

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:16:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-23T21:19:52', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'b43326a5-bc74-439e-8671-c41b8e20d5f8'	System	24 Aug 2020 02:20:17
User entered 'None (0)'	System	24 Aug 2020 02:20:17

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:16:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-23T21:19:55', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'b43326a5-bc74-439e-8671-c41b8e20d5f8'	System	24 Aug 2020 02:20:17
User entered 'None (0)'	System	24 Aug 2020 02:20:17

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:16:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-23T21:19:58', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'b43326a5-bc74-439e-8671-c41b8e20d5f8'	System	24 Aug 2020 02:20:17
User entered 'None (0)'	System	24 Aug 2020 02:20:17

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:16:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-23T21:20:00', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'b43326a5-bc74-439e-8671-c41b8e20d5f8'	System	24 Aug 2020 02:20:17
User entered 'None (0)'	System	24 Aug 2020 02:20:17

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:16:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-23T21:20:03', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'b43326a5-bc74-439e-8671-c41b8e20d5f8'	System	24 Aug 2020 02:20:17
User entered 'None (0)'	System	24 Aug 2020 02:20:17

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:16:12

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)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-23T21:20:06', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'b43326a5-bc74-439e-8671-c41b8e20d5f8'	System	24 Aug 2020 02:20:17
User entered 'No (N)'	System	24 Aug 2020 02:20:17

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:16:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-23T21:20:13', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'b43326a5-bc74-439e-8671-c41b8e20d5f8'	System	24 Aug 2020 02:20:17
User entered '23 Aug 2020 21:20'	System	24 Aug 2020 02:20:17

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:16:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:16:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
Data entry locked.	System	20 Aug 2020 21:15:38
User entered 'Day 5'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:16:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-24T21:16:32', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'd1ff2934-7790-4db4-ace3-e296e266c2d7'	System	25 Aug 2020 02:17:06
User entered 'None (0)'	System	25 Aug 2020 02:17:06

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:16:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-24T21:16:35', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'd1ff2934-7790-4db4-ace3-e296e266c2d7'	System	25 Aug 2020 02:17:06
User entered 'None (0)'	System	25 Aug 2020 02:17:06

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:16:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-24T21:16:38', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'd1ff2934-7790-4db4-ace3-e296e266c2d7'	System	25 Aug 2020 02:17:06
User entered 'None (0)'	System	25 Aug 2020 02:17:06

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:16:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-24T21:16:43', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'd1ff2934-7790-4db4-ace3-e296e266c2d7'	System	25 Aug 2020 02:17:06
User entered 'None (0)'	System	25 Aug 2020 02:17:06

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:16:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-24T21:16:46', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'd1ff2934-7790-4db4-ace3-e296e266c2d7'	System	25 Aug 2020 02:17:06
User entered 'None (0)'	System	25 Aug 2020 02:17:06

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:16:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-24T21:16:49', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'd1ff2934-7790-4db4-ace3-e296e266c2d7'	System	25 Aug 2020 02:17:06
User entered 'None (0)'	System	25 Aug 2020 02:17:06

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:16:12

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)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-24T21:16:57', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'd1ff2934-7790-4db4-ace3-e296e266c2d7'	System	25 Aug 2020 02:17:06
User entered 'No (N)'	System	25 Aug 2020 02:17:06

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:16:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-24T21:17:04', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'd1ff2934-7790-4db4-ace3-e296e266c2d7'	System	25 Aug 2020 02:17:06
User entered '24 Aug 2020 21:17'	System	25 Aug 2020 02:17:06

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:16:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:16:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
Data entry locked.	System	20 Aug 2020 21:15:38
User entered 'Day 6'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:16:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-26T00:11:19', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '36e6185c-2a1e-4bb5-91de-a264c8b7ac0f'	System	26 Aug 2020 05:11:51
User entered 'None (0)'	System	26 Aug 2020 05:11:51

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:16:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-26T00:11:24', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '36e6185c-2a1e-4bb5-91de-a264c8b7ac0f'	System	26 Aug 2020 05:11:51
User entered 'None (0)'	System	26 Aug 2020 05:11:51

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:16:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-26T00:11:26', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '36e6185c-2a1e-4bb5-91de-a264c8b7ac0f'	System	26 Aug 2020 05:11:51
User entered 'None (0)'	System	26 Aug 2020 05:11:51

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:16:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-26T00:11:30', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '36e6185c-2a1e-4bb5-91de-a264c8b7ac0f'	System	26 Aug 2020 05:11:51
User entered 'None (0)'	System	26 Aug 2020 05:11:51

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:16:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-26T00:11:33', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '36e6185c-2a1e-4bb5-91de-a264c8b7ac0f'	System	26 Aug 2020 05:11:51
User entered 'None (0)'	System	26 Aug 2020 05:11:51

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:16:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-26T00:11:38', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '36e6185c-2a1e-4bb5-91de-a264c8b7ac0f'	System	26 Aug 2020 05:11:51
User entered 'None (0)'	System	26 Aug 2020 05:11:51

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:16:12

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)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-26T00:11:41', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '36e6185c-2a1e-4bb5-91de-a264c8b7ac0f'	System	26 Aug 2020 05:11:51
User entered 'No (N)'	System	26 Aug 2020 05:11:51

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:16:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-26T00:11:47', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '36e6185c-2a1e-4bb5-91de-a264c8b7ac0f'	System	26 Aug 2020 05:11:51
User entered '26 Aug 2020 00:11'	System	26 Aug 2020 05:11:51

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:16:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:16:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
Data entry locked.	System	20 Aug 2020 21:15:38
User entered 'Day 7'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:16:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-27T00:02:29', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '209824a2-0c28-4c11-a2ea-002dc493e1c0'	System	27 Aug 2020 05:02:56
User entered 'None (0)'	System	27 Aug 2020 05:02:56

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:16:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-27T00:02:32', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '209824a2-0c28-4c11-a2ea-002dc493e1c0'	System	27 Aug 2020 05:02:56
User entered 'None (0)'	System	27 Aug 2020 05:02:56

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:16:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-27T00:02:35', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '209824a2-0c28-4c11-a2ea-002dc493e1c0'	System	27 Aug 2020 05:02:56
User entered 'None (0)'	System	27 Aug 2020 05:02:56

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:16:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-27T00:02:38', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '209824a2-0c28-4c11-a2ea-002dc493e1c0'	System	27 Aug 2020 05:02:56
User entered 'None (0)'	System	27 Aug 2020 05:02:56

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:16:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-27T00:02:41', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '209824a2-0c28-4c11-a2ea-002dc493e1c0'	System	27 Aug 2020 05:02:56
User entered 'None (0)'	System	27 Aug 2020 05:02:56

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:16:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-27T00:02:44', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '209824a2-0c28-4c11-a2ea-002dc493e1c0'	System	27 Aug 2020 05:02:56
User entered 'None (0)'	System	27 Aug 2020 05:02:56

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:16:12

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)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-27T00:02:47', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '209824a2-0c28-4c11-a2ea-002dc493e1c0'	System	27 Aug 2020 05:02:56
User entered 'No (N)'	System	27 Aug 2020 05:02:56

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:16:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-08-27T00:02:53', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '209824a2-0c28-4c11-a2ea-002dc493e1c0'	System	27 Aug 2020 05:02:56
User entered '27 Aug 2020 00:02'	System	27 Aug 2020 05:02:56

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:16:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 21:15:38

US3312201

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:16:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 21:15:38

US3312201

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:56:01

US3312201

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '27 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:56:01

US3312201

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:56:01

US3312201

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered empty.	(b) (4)	28 Aug 2020 17:56:01
	Karol Moore (b) (4)	
	(b) (4)	

US3312201

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:56:08

US3312201

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User entered 'I'	System	28 Aug 2020 17:56:08

US3312201

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	04 Sep 2020 14:13:18

US3312201

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '3 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	04 Sep 2020 14:13:18

US3312201

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	04 Sep 2020 14:13:18

US3312201

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered empty.	(b) (4)	04 Sep 2020 14:13:18
	Karol Moore (b) (4)	
	(b) (4)	

US3312201

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	04 Sep 2020 14:13:22

US3312201

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:31:54
User entered 'I'	System	04 Sep 2020 14:13:22

US3312201

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:08
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 20:54:47

US3312201

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:08
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '10 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 20:54:47

US3312201

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:08
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4)	10 Sep 2020 20:54:47

US3312201

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:08
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 20:54:47

US3312201

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:08
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	10 Sep 2020 20:54:50

US3312201

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:08
User entered 'I'	System	10 Sep 2020 20:54:50

US3312201

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:15:22

US3312201

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '17 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:15:22

US3312201

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:12

[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 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Clinic (Clinic)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:15:22

US3312201

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User entered 'VISIT2'	System	06 Oct 2020 18:15:22

US3312201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4)	06 Oct 2020 18:16:02
	(b) (4)	

US3312201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:16:02

US3312201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '17 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:16:02

US3312201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '14:29'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:16:02

US3312201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User entered '17 Sep 2020 14:29'	System	06 Oct 2020 18:16:02

US3312201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '98.2' F	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:16:02

US3312201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:16:02

US3312201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:16:02

US3312201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '98'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:16:02

US3312201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User entered 'bpm'	System	06 Oct 2020 18:16:02

US3312201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '16'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:16:02

US3312201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User entered 'breaths/min'	System	06 Oct 2020 18:16:02

US3312201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '142'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:16:02

US3312201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User entered 'mmHg'	System	06 Oct 2020 18:16:02

US3312201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '91'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:16:02

US3312201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User entered 'mmHg'	System	06 Oct 2020 18:16:02

US3312201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:16:02

US3312201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:16:02

US3312201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:16:02

US3312201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:16:02

US3312201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User entered empty.	System	06 Oct 2020 18:16:02

US3312201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:16:02

US3312201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:16:02

US3312201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:16:02

US3312201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:16:02

US3312201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User entered empty.	System	06 Oct 2020 18:16:02

US3312201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered empty.	(b) (4) Karol Moore (b) (4)	06 Oct 2020 18:16:02

US3312201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User entered empty.	System	06 Oct 2020 18:16:02

US3312201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:16:02

US3312201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User entered empty.	System	06 Oct 2020 18:16:02

US3312201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:16:02

US3312201

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User entered empty.	System	06 Oct 2020 18:16:02

US3312201

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:16:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:16:14

US3312201

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:16:12

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '17 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:16:14

US3312201

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:18:53

US3312201

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	Karol Moore (b) (4)	06 Oct 2020 18:18:53

US3312201

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

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 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:18:53

US3312201

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User entered empty.	System	06 Oct 2020 18:18:53

US3312201

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered empty.	(b) (4) Karol Moore (b) (4)	06 Oct 2020 18:18:53

US3312201

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:18:53

US3312201

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User entered empty.	System	06 Oct 2020 18:18:53

US3312201

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered empty.	(b) (4) Karol Moore (b) (4)	06 Oct 2020 18:18:53

US3312201

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User entered empty.	System	06 Oct 2020 18:18:53

US3312201

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User entered empty.	System	06 Oct 2020 18:18:53

US3312201

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	06 Oct 2020 18:19:06

US3312201

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '17 Sep 2020'	(b) (4) Karol Moore (b) (4)	06 Oct 2020 18:19:06

US3312201

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '14:56'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:19:06

US3312201

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User entered '17 Sep 2020 14:56'	System	06 Oct 2020 18:19:06

US3312201

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:16:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '17 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:19:17

US3312201

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:16:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:19:17

US3312201

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:16:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:19:17

US3312201

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:16:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '14:50'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:19:17

US3312201

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User entered '17 Sep 2020 14:50'	System	06 Oct 2020 18:19:17

US3312201

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:16:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:19:17

US3312201

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:16:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:19:17

US3312201

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:16:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:19:17

US3312201

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User entered empty.	System	06 Oct 2020 18:19:17

US3312201

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	06 Oct 2020 18:19:20

US3312201

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User entered '1'	System	06 Oct 2020 18:19:20

US3312201

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:00:07

US3312201

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:00:07

US3312201

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:00:07

US3312201

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:00:07

US3312201

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:00:11

US3312201

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User entered 'I'	System	09 Oct 2020 14:00:11

US3312201

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:00:46

US3312201

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '1 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:00:46

US3312201

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:00:46

US3312201

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:00:46

US3312201

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:01:42

US3312201

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User entered 'I'	System	09 Oct 2020 14:01:42

US3312201

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:02:00

US3312201

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:02:00

US3312201

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:02:00

US3312201

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:02:00

US3312201

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:02:05

US3312201

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User entered 'I'	System	09 Oct 2020 14:02:05

US3312201

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:34
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:10:11

US3312201

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:34
User entered '28 Oct 2020'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:10:11

US3312201

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:12

[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 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:34
User entered 'Clinic (Clinic)'	(b) (4) Monica Atwood (b) (4) (b) (4)	02 Nov 2020 16:10:11

US3312201

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User entered 'VISIT3'	System	02 Nov 2020 16:10:11

US3312201

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:34
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:10:52

US3312201

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:34
User entered '28 Oct 2020'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:10:52

US3312201

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:34
User entered '11:51'	(b) (4) Monica Atwood (b) (4) (b) (4)	02 Nov 2020 16:10:52

US3312201

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User entered '28 Oct 2020 11:51'	System	02 Nov 2020 16:10:52

US3312201

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:34
User entered '98.7' F	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:10:52

US3312201

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:34
User entered 'Oral (Oral)'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:10:52

US3312201

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:34
User entered empty.	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:10:52

US3312201

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:34
User entered '93'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:10:52

US3312201

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User entered 'bpm'	System	02 Nov 2020 16:10:52

US3312201

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:34
User entered '14'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:10:52

US3312201

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User entered 'breaths/min'	System	02 Nov 2020 16:10:52

US3312201

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:34
User entered '175'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:10:52

US3312201

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User entered 'mmHg'	System	02 Nov 2020 16:10:52

US3312201

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:34
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 04:06:40
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'CS, AE PAGE UPDATED' (Site from System).	Monica Atwood (b) (4) (b) (4)	02 Nov 2020 16:11:11
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		02 Nov 2020 16:10:52
User entered '109'	Monica Atwood (b) (4) (b) (4)	02 Nov 2020 16:10:52

US3312201

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User entered 'mmHg'	System	02 Nov 2020 16:10:52

US3312201

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52

US3312201

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52

US3312201

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:16:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:34
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:11:23

US3312201

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:16:12

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:34
User entered '28 Oct 2020'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:11:23

US3312201

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:34
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:11:40

US3312201

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:34
User entered '28 Oct 2020'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:11:40

US3312201

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:34
User entered '12:39'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:11:40

US3312201

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User entered '28 Oct 2020 12:39'	System	02 Nov 2020 16:11:40

US3312201

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:07:13
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:11:45

US3312201

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User entered 'I'	System	02 Nov 2020 16:11:45

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
Data entry locked.	System	20 Aug 2020 21:15:38
User entered 'Day 64'	System	20 Aug 2020 21:15:38

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Have you had 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 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-10-23T14:44:33', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '20a79dbc-3dcf-4d1f-a5c0-ebbc33092351'	System	23 Oct 2020 19:45:15
User entered 'Yes (Y)'	System	23 Oct 2020 19:45:15

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Have you been exposed to someone with known SARS-CoV-2 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 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-10-23T14:44:36', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '20a79dbc-3dcf-4d1f-a5c0-ebbc33092351'	System	23 Oct 2020 19:45:15
User entered 'No (N)'	System	23 Oct 2020 19:45:15

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Have you experienced any 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 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-10-23T14:44:40', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '20a79dbc-3dcf-4d1f-a5c0-ebbc33092351'	System	23 Oct 2020 19:45:15
User entered 'No (N)'	System	23 Oct 2020 19:45:15

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Have you had 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 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-10-23T14:44:48', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '20a79dbc-3dcf-4d1f-a5c0-ebbc33092351'	System	23 Oct 2020 19:45:15
User entered 'Yes (Y)'	System	23 Oct 2020 19:45:15

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Please contact your study clinic 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 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-10-23T14:44:56', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '20a79dbc-3dcf-4d1f-a5c0-ebbc33092351'	System	23 Oct 2020 19:45:15
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Oct 2020 19:45:15

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-10-23T14:45:04', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '20a79dbc-3dcf-4d1f-a5c0-ebbc33092351'	System	23 Oct 2020 19:45:15
User entered '23 Oct 2020 14:45:04'	System	23 Oct 2020 19:45:15

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
Data entry locked.	System	20 Aug 2020 21:15:38
User entered '20 Oct 2020 00:01'	System	20 Aug 2020 21:15:38

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
Data entry locked.	System	20 Aug 2020 21:15:38
User entered '24 Oct 2020 23:59'	System	20 Aug 2020 21:15:38

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
Data entry locked.	System	20 Aug 2020 21:15:38
User entered 'Day 71'	System	20 Aug 2020 21:15:38

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Have you had 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 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-10-27T09:24:13', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '12705520-438b-4543-a21e-5291bdee536f'	System	27 Oct 2020 14:24:27
User entered 'No (N)'	System	27 Oct 2020 14:24:27

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Have you been exposed to someone with known SARS-CoV-2 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 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-10-27T09:24:17', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '12705520-438b-4543-a21e-5291bdee536f'	System	27 Oct 2020 14:24:27
User entered 'No (N)'	System	27 Oct 2020 14:24:27

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-10-27T09:24:22', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '12705520-438b-4543-a21e-5291bdee536f' User entered '27 Oct 2020 09:24:22'	System	27 Oct 2020 14:24:27
	System	27 Oct 2020 14:24:27

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
Data entry locked.	System	20 Aug 2020 21:15:38
User entered '27 Oct 2020 00:01'	System	20 Aug 2020 21:15:38

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
Data entry locked.	System	20 Aug 2020 21:15:38
User entered '31 Oct 2020 23:59'	System	20 Aug 2020 21:15:38

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
Data entry locked.	System	20 Aug 2020 21:15:38
User entered 'Day 78'	System	20 Aug 2020 21:15:38

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Have you had 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 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-11-05T20:33:30', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '193e4512-6b93-41ee-9922-33185ef831cf'	System	06 Nov 2020 02:33:42
User entered 'No (N)'	System	06 Nov 2020 02:33:42

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Have you been exposed to someone with known SARS-CoV-2 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 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-11-05T20:33:34', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '193e4512-6b93-41ee-9922-33185ef831cf'	System	06 Nov 2020 02:33:42
User entered 'No (N)'	System	06 Nov 2020 02:33:42

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-11-05T20:33:39', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '193e4512-6b93-41ee-9922-33185ef831cf'	System	06 Nov 2020 02:33:42
User entered '05 Nov 2020 20:33:39'	System	06 Nov 2020 02:33:42

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
Data entry locked.	System	20 Aug 2020 21:15:38
User entered '03 Nov 2020 00:01'	System	20 Aug 2020 21:15:38

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:59:31
Data entry locked.	System	20 Aug 2020 21:15:38
User entered '07 Nov 2020 23:59'	System	20 Aug 2020 21:15:38

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:09:06
Data entry locked.	System	20 Aug 2020 21:15:38
User entered 'Day 92'	System	20 Aug 2020 21:15:38

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Have you had 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)	24 Apr 2021 05:50:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:09:06

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Have you been exposed to someone with known SARS-CoV-2 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)	24 Apr 2021 05:50:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:09:06

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Please contact your study clinic 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)	24 Apr 2021 05:50:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:09:06

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Have you experienced any 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)	24 Apr 2021 05:50:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:09:06

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:09:06

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:09:06

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:09:06

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:09:06

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:09:06

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:09:06

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:09:06

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:09:06

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:09:06

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:09:06

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:09:06

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:09:06

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:09:06

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:09:06

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:09:06

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:09:06

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:09:06

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Please contact your study clinic 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)	24 Apr 2021 05:50:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:09:06

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Have you had 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)	24 Apr 2021 05:50:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:09:06

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Please contact your study clinic 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)	24 Apr 2021 05:50:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:09:06

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:09:06

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:09:06
Data entry locked.	System	20 Aug 2020 21:15:38
User entered '17 Nov 2020 00:01'	System	20 Aug 2020 21:15:38

US3312201

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:09:06
Data entry locked.	System	20 Aug 2020 21:15:38
User entered '21 Nov 2020 23:59'	System	20 Aug 2020 21:15:38

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Have you had 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 (8b4ce5918f603bdf)', Time: '2020-12-07T13:25:26', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '435aec50-f15c-4b7c-85ad-4d37b9b9a610'	System	07 Dec 2020 19:26:02
User entered 'No (N)'	System	07 Dec 2020 19:26:02

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Have you been exposed to someone with known SARS-CoV-2 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 (8b4ce5918f603bdf)', Time: '2020-12-07T13:25:32', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '435aec50-f15c-4b7c-85ad-4d37b9b9a610'	System	07 Dec 2020 19:26:02
User entered 'No (N)'	System	07 Dec 2020 19:26:02

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b4ce5918f603bdf)', Time: '2020-12-07T13:25:43', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '435aec50-f15c-4b7c-85ad-4d37b9b9a610' User entered '07 Dec 2020 13:25:43'	System	07 Dec 2020 19:26:02

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Have you had 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 (563ea30a98464de9)', Time: '2020-12-16T10:51:51', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'b36ff06c-6ccc-4a4a-9494-2edf2c06d1cb'	System	16 Dec 2020 16:52:15
User entered 'No (N)'	System	16 Dec 2020 16:52:15

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Have you been exposed to someone with known SARS-CoV-2 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 (563ea30a98464de9)', Time: '2020-12-16T10:51:58', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'b36ff06c-6ccc-4a4a-9494-2edf2c06d1cb'	System	16 Dec 2020 16:52:15
User entered 'No (N)'	System	16 Dec 2020 16:52:15

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (563ea30a98464de9)', Time: '2020-12-16T10:52:08', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'b36ff06c-6ccc-4a4a-9494-2edf2c06d1cb' User entered '16 Dec 2020 10:52:08'	System	16 Dec 2020 16:52:15
	System	16 Dec 2020 16:52:15

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Have you had 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 (563ea30a98464de9)', Time: '2020-12-21T18:25:13', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '9892eed4-77b5-421b-900e-36b591761391'	System	22 Dec 2020 00:25:40
User entered 'No (N)'	System	22 Dec 2020 00:25:40

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Have you been exposed to someone with known SARS-CoV-2 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 (563ea30a98464de9)', Time: '2020-12-21T18:25:21', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '9892eed4-77b5-421b-900e-36b591761391'	System	22 Dec 2020 00:25:40
User entered 'No (N)'	System	22 Dec 2020 00:25:40

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (563ea30a98464de9)', Time: '2020-12-21T18:25:34', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '9892eed4-77b5-421b-900e-36b591761391'	System	22 Dec 2020 00:25:40
User entered '21 Dec 2020 18:25:34'	System	22 Dec 2020 00:25:40

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Have you had 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 (563ea30a98464de9)', Time: '2020-12-29T13:03:51', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '6cbcac07-31b5-4a53-8937-39b8b4a20615'	System	29 Dec 2020 19:04:09
User entered 'No (N)'	System	29 Dec 2020 19:04:09

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Have you been exposed to someone with known SARS-CoV-2 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 (563ea30a98464de9)', Time: '2020-12-29T13:03:54', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '6cbcac07-31b5-4a53-8937-39b8b4a20615'	System	29 Dec 2020 19:04:09
User entered 'No (N)'	System	29 Dec 2020 19:04:09

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (563ea30a98464de9)', Time: '2020-12-29T13:04:04', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '6cbcac07-31b5-4a53-8937-39b8b4a20615' User entered '29 Dec 2020 13:04:04'	System	29 Dec 2020 19:04:09
	System	29 Dec 2020 19:04:09

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Have you had 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 (563ea30a98464de9)', Time: '2021-01-05T10:44:07', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'bd023eb1-8c22-485a-b8f2-e3cb688ad1cf'	System	05 Jan 2021 16:44:23
User entered 'No (N)'	System	05 Jan 2021 16:44:23

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Have you been exposed to someone with known SARS-CoV-2 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 (563ea30a98464de9)', Time: '2021-01-05T10:44:14', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'bd023eb1-8c22-485a-b8f2-e3cb688ad1cf'	System	05 Jan 2021 16:44:23
User entered 'No (N)'	System	05 Jan 2021 16:44:23

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (563ea30a98464de9)', Time: '2021-01-05T10:44:20', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'bd023eb1-8c22-485a-b8f2-e3cb688ad1cf'	System	05 Jan 2021 16:44:23
User entered '05 Jan 2021 10:44:20'	System	05 Jan 2021 16:44:23

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Have you had 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 (3a62e277055af890)', Time: '2021-01-12T22:36:46', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '571e0108-5bea-4c7b-8c5c-d94181896214'	System	13 Jan 2021 04:37:11
User entered 'No (N)'	System	13 Jan 2021 04:37:11

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Have you been exposed to someone with known SARS-CoV-2 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 (3a62e277055af890)', Time: '2021-01-12T22:36:52', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '571e0108-5bea-4c7b-8c5c-d94181896214'	System	13 Jan 2021 04:37:11
User entered 'No (N)'	System	13 Jan 2021 04:37:11

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a62e277055af890)', Time: '2021-01-12T22:37:02', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '571e0108-5bea-4c7b-8c5c-d94181896214'	System	13 Jan 2021 04:37:11
User entered '12 Jan 2021 22:37:02'	System	13 Jan 2021 04:37:11

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Have you had 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 (3a62e277055af890)', Time: '2021-01-16T00:07:10', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '2ffde5e4-952c-444a-9706-53e1005b6975'	System	16 Jan 2021 06:07:30
User entered 'No (N)'	System	16 Jan 2021 06:07:30

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Have you been exposed to someone with known SARS-CoV-2 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 (3a62e277055af890)', Time: '2021-01-16T00:07:17', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '2ffde5e4-952c-444a-9706-53e1005b6975'	System	16 Jan 2021 06:07:30
User entered 'No (N)'	System	16 Jan 2021 06:07:30

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a62e277055af890)', Time: '2021-01-16T00:07:26', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '2ffde5e4-952c-444a-9706-53e1005b6975'	System	16 Jan 2021 06:07:30
User entered '16 Jan 2021 00:07:26'	System	16 Jan 2021 06:07:30

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Have you had 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 (3a62e277055af890)', Time: '2021-01-23T12:37:07', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '03d08bdd-8aa4-47f7-9b11-4e3956bf17d8'	System	23 Jan 2021 18:37:28
User entered 'No (N)'	System	23 Jan 2021 18:37:28

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Have you been exposed to someone with known SARS-CoV-2 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 (3a62e277055af890)', Time: '2021-01-23T12:37:17', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '03d08bdd-8aa4-47f7-9b11-4e3956bf17d8'	System	23 Jan 2021 18:37:28
User entered 'No (N)'	System	23 Jan 2021 18:37:28

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a62e277055af890)', Time: '2021-01-23T12:37:25', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '03d08bdd-8aa4-47f7-9b11-4e3956bf17d8'	System	23 Jan 2021 18:37:28
User entered '23 Jan 2021 12:37:25'	System	23 Jan 2021 18:37:28

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Have you had 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 (3a62e277055af890)', Time: '2021-02-01T12:00:38', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '59ace3d0-b56b-4cae-b66c-45f554f9dff8'	System	01 Feb 2021 18:01:57
User entered 'No (N)'	System	01 Feb 2021 18:01:57

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Have you been exposed to someone with known SARS-CoV-2 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 (3a62e277055af890)', Time: '2021-02-01T12:00:41', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '59ace3d0-b56b-4cae-b66c-45f554f9dff8'	System	01 Feb 2021 18:01:57
User entered 'No (N)'	System	01 Feb 2021 18:01:57

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a62e277055af890)', Time: '2021-02-01T12:00:46', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '59ace3d0-b56b-4cae-b66c-45f554f9dff8'	System	01 Feb 2021 18:01:57
User entered '01 Feb 2021 12:00:46'	System	01 Feb 2021 18:01:57

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Have you had 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 (3a62e277055af890)', Time: '2021-02-08T10:18:14', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '51fafda7-03e5-44f2-9299-07d9d6f3a559'	System	08 Feb 2021 16:18:29
User entered 'No (N)'	System	08 Feb 2021 16:18:29

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Have you been exposed to someone with known SARS-CoV-2 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 (3a62e277055af890)', Time: '2021-02-08T10:18:18', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '51fafda7-03e5-44f2-9299-07d9d6f3a559'	System	08 Feb 2021 16:18:29
User entered 'No (N)'	System	08 Feb 2021 16:18:29

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a62e277055af890)', Time: '2021-02-08T10:18:24', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '51fafda7-03e5-44f2-9299-07d9d6f3a559'	System	08 Feb 2021 16:18:29
User entered '08 Feb 2021 10:18:24'	System	08 Feb 2021 16:18:29

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Have you had 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 (3a62e277055af890)', Time: '2021-02-13T01:49:50', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '331474f7-3419-43c3-9a29-51aef612bca5'	System	13 Feb 2021 07:50:07
User entered 'No (N)'	System	13 Feb 2021 07:50:07

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Have you been exposed to someone with known SARS-CoV-2 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 (3a62e277055af890)', Time: '2021-02-13T01:49:53', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '331474f7-3419-43c3-9a29-51aef612bca5'	System	13 Feb 2021 07:50:07
User entered 'No (N)'	System	13 Feb 2021 07:50:07

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a62e277055af890)', Time: '2021-02-13T01:50:00', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '331474f7-3419-43c3-9a29-51aef612bca5'	System	13 Feb 2021 07:50:07
User entered '13 Feb 2021 01:50:00'	System	13 Feb 2021 07:50:07

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Have you had 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 (3a62e277055af890)', Time: '2021-02-20T09:08:05', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'c3652f59-8575-4ea8-bde0-1e9f111eb1b1'	System	20 Feb 2021 15:08:16
User entered 'No (N)'	System	20 Feb 2021 15:08:16

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Have you been exposed to someone with known SARS-CoV-2 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 (3a62e277055af890)', Time: '2021-02-20T09:08:09', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'c3652f59-8575-4ea8-bde0-1e9f111eb1b1'	System	20 Feb 2021 15:08:16
User entered 'No (N)'	System	20 Feb 2021 15:08:16

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a62e277055af890)', Time: '2021-02-20T09:08:13', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'c3652f59-8575-4ea8-bde0-1e9f111eb1b1' User entered '20 Feb 2021 09:08:13'	System	20 Feb 2021 15:08:16
	System	20 Feb 2021 15:08:16

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Have you had 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 (3a62e277055af890)', Time: '2021-02-27T00:02:47-06:00', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '1ec6231e-7af3-47b8-a627-903d0e5fc39b'	System	27 Feb 2021 06:03:09
User entered 'No (N)'	System	27 Feb 2021 06:03:09

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Have you been exposed to someone with known SARS-CoV-2 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 (3a62e277055af890)', Time: '2021-02-27T00:02:51-06:00', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '1ec6231e-7af3-47b8-a627-903d0e5fc39b'	System	27 Feb 2021 06:03:09
User entered 'No (N)'	System	27 Feb 2021 06:03:09

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a62e277055af890)', Time: '2021-02-27T00:02:58-06:00', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '1ec6231e-7af3-47b8-a627-903d0e5fc39b'	System	27 Feb 2021 06:03:09
User entered '27 Feb 2021 00:02:58'	System	27 Feb 2021 06:03:09

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Have you had 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 (3a62e277055af890)', Time: '2021-03-06T01:24:36-06:00', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'e8c7225e-2f64-410b-80a2-af582180c084'	System	06 Mar 2021 07:25:29
User entered 'No (N)'	System	06 Mar 2021 07:25:29

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Have you been exposed to someone with known SARS-CoV-2 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 (3a62e277055af890)', Time: '2021-03-06T01:25:17-06:00', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'e8c7225e-2f64-410b-80a2-af582180c084'	System	06 Mar 2021 07:25:29
User entered 'No (N)'	System	06 Mar 2021 07:25:29

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a62e277055af890)', Time: '2021-03-06T01:25:26-06:00', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'e8c7225e-2f64-410b-80a2-af582180c084'	System	06 Mar 2021 07:25:29
User entered '06 Mar 2021 01:25:26'	System	06 Mar 2021 07:25:29

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Have you had 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 (3a62e277055af890)', Time: '2021-03-15T13:27:31-05:00', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '97ca3f2b-ed35-4577-9368-7caceeb0e749'	System	15 Mar 2021 18:27:45
User entered 'No (N)'	System	15 Mar 2021 18:27:45

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Have you been exposed to someone with known SARS-CoV-2 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 (3a62e277055af890)', Time: '2021-03-15T13:27:36-05:00', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '97ca3f2b-ed35-4577-9368-7caceeb0e749'	System	15 Mar 2021 18:27:45
User entered 'No (N)'	System	15 Mar 2021 18:27:45

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a62e277055af890)', Time: '2021-03-15T13:27:41-05:00', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '97ca3f2b-ed35-4577-9368-7caceeb0e749' User entered '15 Mar 2021 13:27:41'	System	15 Mar 2021 18:27:45
	System	15 Mar 2021 18:27:45

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Have you had 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 (3a62e277055af890)', Time: '2021-03-22T16:39:46-05:00', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'd1ae7d75-1fa1-4ef6-863e-ae760d836578'	System	22 Mar 2021 21:40:00
User entered 'No (N)'	System	22 Mar 2021 21:40:00

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Have you been exposed to someone with known SARS-CoV-2 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 (3a62e277055af890)', Time: '2021-03-22T16:39:50-05:00', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'd1ae7d75-1fa1-4ef6-863e-ae760d836578'	System	22 Mar 2021 21:40:00
User entered 'No (N)'	System	22 Mar 2021 21:40:00

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a62e277055af890)', Time: '2021-03-22T16:39:55-05:00', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'd1ae7d75-1fa1-4ef6-863e-ae760d836578' User entered '22 Mar 2021 16:39:55'	System	22 Mar 2021 21:40:00

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Have you had 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 (3a62e277055af890)', Time: '2021-03-28T23:35:03-05:00', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '55b76509-2015-4404-8660-5df90fb90a0b' User entered 'Yes (Y)'	System	29 Mar 2021 04:35:43
	System	29 Mar 2021 04:35:43

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Have you been exposed to someone with known SARS-CoV-2 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 (3a62e277055af890)', Time: '2021-03-28T23:35:09-05:00', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '55b76509-2015-4404-8660-5df90fb90a0b'	System	29 Mar 2021 04:35:43
User entered 'No (N)'	System	29 Mar 2021 04:35:43

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a62e277055af890)', Time: '2021-03-28T23:35:15-05:00', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '55b76509-2015-4404-8660-5df90fb90a0b' User entered 'No (N)'	System	29 Mar 2021 04:35:43
	System	29 Mar 2021 04:35:43

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a62e277055af890)', Time: '2021-03-28T23:35:18-05:00', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '55b76509-2015-4404-8660-5df90fb90a0b'	System	29 Mar 2021 04:35:43
User entered 'No (N)'	System	29 Mar 2021 04:35:43

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a62e277055af890)', Time: '2021-03-28T23:35:39-05:00', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '55b76509-2015-4404-8660-5df90fb90a0b' User entered '28 Mar 2021 23:35:39'	System	29 Mar 2021 04:35:43

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Have you had 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 (3a62e277055af890)', Time: '2021-04-03T00:44:34-05:00', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '370dde91-f94d-4dd3-b295-05bb2de359ec' User entered 'No (N)'	System	03 Apr 2021 05:46:46
	System	03 Apr 2021 05:46:46

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Have you been exposed to someone with known SARS-CoV-2 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 (3a62e277055af890)', Time: '2021-04-03T00:44:38-05:00', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '370dde91-f94d-4dd3-b295-05bb2de359ec'	System	03 Apr 2021 05:46:46
User entered 'No (N)'	System	03 Apr 2021 05:46:46

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a62e277055af890)', Time: '2021-04-03T00:44:44-05:00', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '370dde91-f94d-4dd3-b295-05bb2de359ec'	System	03 Apr 2021 05:46:46
User entered '03 Apr 2021 00:44:44'	System	03 Apr 2021 05:46:46

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Have you had 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 (3a62e277055af890)', Time: '2021-04-12T11:45:35-05:00', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'a0f51d84-111d-4025-a5a0-802eed6a17a9'	System	12 Apr 2021 16:45:51
User entered 'No (N)'	System	12 Apr 2021 16:45:51

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Have you been exposed to someone with known SARS-CoV-2 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 (3a62e277055af890)', Time: '2021-04-12T11:45:39-05:00', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'a0f51d84-111d-4025-a5a0-802eed6a17a9'	System	12 Apr 2021 16:45:51
User entered 'No (N)'	System	12 Apr 2021 16:45:51

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a62e277055af890)', Time: '2021-04-12T11:45:44-05:00', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'a0f51d84-111d-4025-a5a0-802eed6a17a9'	System	12 Apr 2021 16:45:51
User entered '12 Apr 2021 11:45:44'	System	12 Apr 2021 16:45:51

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Have you had 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 (3a62e277055af890)', Time: '2021-04-17T10:26:33-05:00', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '3a69bc54-e781-4ed6-9e7d-54c087b6ebbc' User entered 'No (N)'	System	17 Apr 2021 15:26:45
	System	17 Apr 2021 15:26:45

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Have you been exposed to someone with known SARS-CoV-2 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 (3a62e277055af890)', Time: '2021-04-17T10:26:37-05:00', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '3a69bc54-e781-4ed6-9e7d-54c087b6ebbc' User entered 'No (N)'	System	17 Apr 2021 15:26:45
	System	17 Apr 2021 15:26:45

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a62e277055af890)', Time: '2021-04-17T10:26:42-05:00', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '3a69bc54-e781-4ed6-9e7d-54c087b6ebbc' User entered '17 Apr 2021 10:26:42'	System	17 Apr 2021 15:26:45
	System	17 Apr 2021 15:26:45

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Have you had 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 (3a62e277055af890)', Time: '2021-04-24T19:08:31-05:00', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'c224221b-ac47-4d75-a3db-be8c7f272ec3'	System	25 Apr 2021 00:08:44
User entered 'No (N)'	System	25 Apr 2021 00:08:44

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

Have you been exposed to someone with known SARS-CoV-2 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 (3a62e277055af890)', Time: '2021-04-24T19:08:35-05:00', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'c224221b-ac47-4d75-a3db-be8c7f272ec3'	System	25 Apr 2021 00:08:44
User entered 'No (N)'	System	25 Apr 2021 00:08:44

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a62e277055af890)', Time: '2021-04-24T19:08:39-05:00', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: 'c224221b-ac47-4d75-a3db-be8c7f272ec3'	System	25 Apr 2021 00:08:44
User entered '24 Apr 2021 19:08:39'	System	25 Apr 2021 00:08:44

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Have you had 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 (3a62e277055af890)', Time: '2021-05-02T13:50:47-05:00', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '85474e0b-3734-4e1d-9da3-277b72f5df51'	System	02 May 2021 18:51:01
User entered 'No (N)'	System	02 May 2021 18:51:01

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Have you been exposed to someone with known SARS-CoV-2 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 (3a62e277055af890)', Time: '2021-05-02T13:50:51-05:00', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '85474e0b-3734-4e1d-9da3-277b72f5df51'	System	02 May 2021 18:51:01
User entered 'No (N)'	System	02 May 2021 18:51:01

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a62e277055af890)', Time: '2021-05-02T13:50:55-05:00', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '85474e0b-3734-4e1d-9da3-277b72f5df51'	System	02 May 2021 18:51:01
User entered '02 May 2021 13:50:55'	System	02 May 2021 18:51:01

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 00:09:06

US3312201

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:09:06
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 00:09:06

US3312201

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:16:12

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a62e277055af890)', Time: '2021-03-01T13:09:52-06:00', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '0746c121-eb0f-465c-bdd3-65fc10189995'	System	01 Mar 2021 19:09:59
User entered 'No (N)'	System	01 Mar 2021 19:09:59

US3312201

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:16:12

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a62e277055af890)', Time: '2021-03-01T13:09:56-06:00', User OID: 'PatientReportedOutcome (US3312201)', ODM File OID: '0746c121-eb0f-465c-bdd3-65fc10189995'	System	01 Mar 2021 19:09:59
User entered '01 Mar 2021 13:09:56'	System	01 Mar 2021 19:09:59

US3312201

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4)	12 Nov 2020 19:10:09

US3312201

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '12 Nov 2020'	(b) (4) Monica Atwood (b) (4)	12 Nov 2020 19:10:09

US3312201

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Monica Atwood (b) (4)	12 Nov 2020 19:10:09

US3312201

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered empty.	(b) (4) Monica Atwood (b) (4)	12 Nov 2020 19:10:09

US3312201

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4)	12 Nov 2020 19:10:22

US3312201

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:07:52
User entered 'I'	System	12 Nov 2020 19:10:22

US3312201

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 21:35:39

US3312201

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '16 Dec 2020'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 21:35:39

US3312201

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 21:35:39

US3312201

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 21:35:39

US3312201

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 21:35:44

US3312201

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User entered 'I'	System	17 Dec 2020 21:35:44

US3312201

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:49:49

US3312201

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '13 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:49:49

US3312201

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:49:49

US3312201

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered empty.	(b) (4), (b) (6)	15 Jan 2021 18:49:49

US3312201

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:50:02

US3312201

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User entered '1'	System	15 Jan 2021 18:50:02

US3312201

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:42:26

US3312201

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:42:26

US3312201

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:42:26

US3312201

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:42:26

US3312201

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:42:30

US3312201

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User entered '1'	System	17 Feb 2021 15:42:30

US3312201

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:28:42

US3312201

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:54
User entered '10 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:28:42

US3312201

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:12

[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 06:46:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:54
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:28:42

US3312201

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User entered 'VISIT4'	System	11 Mar 2021 17:28:42

US3312201

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:04:41

US3312201

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:54
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:04:41

US3312201

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:54
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:04:41

US3312201

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User entered empty.	System	30 Mar 2021 14:04:41

US3312201

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:54
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:04:41

US3312201

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:54
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:04:41

US3312201

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:54
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:04:41

US3312201

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:54
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:04:41

US3312201

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User entered empty.	System	30 Mar 2021 14:04:41

US3312201

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:54
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:04:41

US3312201

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User entered empty.	System	30 Mar 2021 14:04:41

US3312201

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:54
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:04:41

US3312201

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User entered empty.	System	30 Mar 2021 14:04:41

US3312201

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:54
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:04:41

US3312201

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User entered empty.	System	30 Mar 2021 14:04:41

US3312201

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02

US3312201

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02

US3312201

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:16:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:28:50

US3312201

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:16:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:54
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:28:50

US3312201

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:29:06

US3312201

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:54
User entered '10 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:29:06

US3312201

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:54
User entered '13:43'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:29:06

US3312201

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User entered '10 Mar 2021 13:43'	System	11 Mar 2021 17:29:06

US3312201

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:29:09

US3312201

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:46:02
User entered '1'	System	11 Mar 2021 17:29:09

US3312201

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:19:14

US3312201

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:11
User entered '13 Apr 2021'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:19:14

US3312201

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:19:14

US3312201

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:11
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:19:14

US3312201

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:19:18

US3312201

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Apr 2021 15:19:18

US3312201

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

Form: Visit Date

Generated On: 11 Aug 2021 22:16:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:55:49

US3312201

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

Form: Visit Date

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	15 Jan 2021 17:55:57
User entered '12 Jan 2021' reason for change: Data Entry Error	System	15 Jan 2021 17:55:57
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	15 Jan 2021 17:55:49
User entered '12 Jan 210' (non-conformant).	(b) (4), (b) (6)	15 Jan 2021 17:55:49

US3312201

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

Form: Visit Date

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System). User entered 'Clinic (Clinic)' reason for change:	(b) (4)	
Data Entry Error	System	15 Jan 2021 17:55:57
User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System). User entered empty.	(b) (4), (b) (6)	15 Jan 2021 17:55:57
	System	15 Jan 2021 17:55:49
	(b) (4), (b) (6)	15 Jan 2021 17:55:49

US3312201

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

Form: Visit Date

Generated On: 11 Aug 2021 22:16:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered 'UNBLND_DECIDE'	System	15 Jan 2021 17:55:49

US3312201

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

Form: Unblinding

Generated On: 11 Aug 2021 22:16:12

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:57:23

US3312201

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

Form: Unblinding

Generated On: 11 Aug 2021 22:16:12

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:10
User entered '0'	(b) (4) Karol Moore (b) (4)	08 Apr 2021 18:32:15
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 13:21:37

US3312201

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

Form: Unblinding

Generated On: 11 Aug 2021 22:16:12

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:57:23

US3312201

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

Form: Unblinding

Generated On: 11 Aug 2021 22:16:12

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:10
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 10:54:05
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	08 Apr 2021 18:32:20
User entered 'Amendment 6 or later (Amendment 6 or later)'	Karol Moore (b) (4) (b) (4)	08 Apr 2021 18:32:15
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 12:42:04
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:21:37

US3312201

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

Form: Unblinding

Generated On: 11 Aug 2021 22:16:12

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:57:23

US3312201

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

Form: Unblinding

Generated On: 11 Aug 2021 22:16:12

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:57:23

US3312201

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

Form: Unblinding

Generated On: 11 Aug 2021 22:16:12

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 07:55:09
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	15 Jan 2021 17:57:23

US3312201

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

Form: Unblinding

Generated On: 11 Aug 2021 22:16:12

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 07:55:09
Comment added "Subject did not receive second dose of placebo. Placebo entered in order to populate additional decisions visit page".	(b) (4), (b) (6)	15 Jan 2021 17:57:44
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	15 Jan 2021 17:57:23

US3312201

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

Form: Unblinding

Generated On: 11 Aug 2021 22:16:12

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:57:23

US3312201

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

Form: Unblinding

Generated On: 11 Aug 2021 22:16:12

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered '1'	System	15 Jan 2021 17:57:23

US3312201

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

Form: Unblinding

Generated On: 11 Aug 2021 22:16:12

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered 'I'	System	15 Jan 2021 17:57:23

US3312201

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:16:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:19:29

US3312201

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:16:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:19:29

US3312201

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:16:12

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered empty.	System	15 Jan 2021 18:19:29
DataPoint set to visible.	System	15 Jan 2021 17:57:23

US3312201

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:16:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:19:29

US3312201

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:16:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:19:29

US3312201

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:16:12

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered empty.	System	15 Jan 2021 18:19:29
DataPoint set to visible.	System	15 Jan 2021 17:57:23

US3312201

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	15 Jan 2021 18:19:29

US3312201

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:19:29

US3312201

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:19:29

US3312201

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '13:34'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:19:29

US3312201

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered '12 Jan 2021 13:34'	System	15 Jan 2021 18:19:29

US3312201

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '98.4' F	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:19:29

US3312201

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:19:29

US3312201

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:19:29

US3312201

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '97'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:19:29

US3312201

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered 'bpm'	System	15 Jan 2021 18:19:29

US3312201

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '14'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:19:29

US3312201

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered 'breaths/min'	System	15 Jan 2021 18:19:29

US3312201

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '151'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:19:29

US3312201

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered 'mmHg'	System	15 Jan 2021 18:19:29

US3312201

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '93'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:19:29

US3312201

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered 'mmHg'	System	15 Jan 2021 18:19:29

US3312201

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:16:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:19:29

US3312201

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:16:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:19:29

US3312201

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:16:12

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered empty.	System	15 Jan 2021 18:19:29
DataPoint set to visible.	System	15 Jan 2021 17:57:23

US3312201

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	15 Jan 2021 18:19:29

US3312201

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:19:29

US3312201

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:19:29

US3312201

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '15:13'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:19:29

US3312201

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered '12 Jan 2021 15:13'	System	15 Jan 2021 18:19:29

US3312201

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:19:29

US3312201

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:19:29

US3312201

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:19:29

US3312201

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '90'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:19:29

US3312201

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered 'bpm'	System	15 Jan 2021 18:19:29

US3312201

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '16'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:19:29

US3312201

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered 'breaths/min'	System	15 Jan 2021 18:19:29

US3312201

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '159'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:19:29

US3312201

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered 'mmHg'	System	15 Jan 2021 18:19:29

US3312201

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '99'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:19:29

US3312201

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered 'mmHg'	System	15 Jan 2021 18:19:29

US3312201

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:16:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:30:22

US3312201

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:16:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:30:22

US3312201

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

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:30:46

US3312201

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

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:30:46

US3312201

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

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

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)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:30:46

US3312201

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

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered 'mRNA-1273'	System	15 Jan 2021 18:30:46
DataPoint set to visible.	System	15 Jan 2021 17:57:23

US3312201

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

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:30:46

US3312201

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

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '14:42'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:30:46

US3312201

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

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered '12 Jan 2021 14:42'	System	15 Jan 2021 18:30:46

US3312201

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

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:30:46

US3312201

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

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered 'ONCE'	System	15 Jan 2021 18:30:46

US3312201

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

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered 'INTRAMUSCULAR'	System	15 Jan 2021 18:30:46

US3312201

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:31:49

US3312201

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:31:49

US3312201

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '13:09'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:31:49

US3312201

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered '12 Jan 2021 13:09'	System	15 Jan 2021 18:31:49

US3312201

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:16:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:32:38

US3312201

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:16:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:32:38

US3312201

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:16:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '13:08'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:32:38

US3312201

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered '12 Jan 2021 13:08'	System	15 Jan 2021 18:32:38

US3312201

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

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:32:45

US3312201

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

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered 'I'	System	15 Jan 2021 18:32:45

US3312201

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:30:11

US3312201

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:30:11

US3312201

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:30:11

US3312201

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:30:11

US3312201

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:29:45

US3312201

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered 'I'	System	22 Jan 2021 16:29:45

US3312201

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered 'I'	System	22 Jan 2021 16:29:45
DataPoint set to visible.	System	22 Jan 2021 16:29:45

US3312201

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:50:05

US3312201

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:50:05

US3312201

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:50:05

US3312201

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered 'OLD29'	System	10 Feb 2021 20:50:05

US3312201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	10 Feb 2021 20:51:29

US3312201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:51:29

US3312201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:51:29

US3312201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '13:07'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:51:29

US3312201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered '09 Feb 2021 13:07'	System	10 Feb 2021 20:51:29

US3312201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:51:29

US3312201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:51:29

US3312201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:51:29

US3312201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '99'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:51:29

US3312201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered 'bpm'	System	10 Feb 2021 20:51:29

US3312201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '16'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:51:29

US3312201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered 'breaths/min'	System	10 Feb 2021 20:51:29

US3312201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '154'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:51:29

US3312201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered 'mmHg'	System	10 Feb 2021 20:51:29

US3312201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '91'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:51:29

US3312201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered 'mmHg'	System	10 Feb 2021 20:51:29

US3312201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	10 Feb 2021 20:51:29

US3312201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:51:29

US3312201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:51:29

US3312201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '14:47'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:51:29

US3312201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered '09 Feb 2021 14:47'	System	10 Feb 2021 20:51:29

US3312201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:51:29

US3312201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:51:29

US3312201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:51:29

US3312201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '89'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:51:29

US3312201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered 'bpm'	System	10 Feb 2021 20:51:29

US3312201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '14'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:51:29

US3312201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered 'breaths/min'	System	10 Feb 2021 20:51:29

US3312201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '154'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:51:29

US3312201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered 'mmHg'	System	10 Feb 2021 20:51:29

US3312201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '96'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:51:29

US3312201

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered 'mmHg'	System	10 Feb 2021 20:51:29

US3312201

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:16:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:51:36

US3312201

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:16:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:51:36

US3312201

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:51:46

US3312201

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:51:46

US3312201

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

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)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:51:46

US3312201

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered 'mRNA-1273'	System	10 Feb 2021 20:51:46
DataPoint set to visible.	System	22 Jan 2021 16:29:45

US3312201

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:51:46

US3312201

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '14:16'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:51:46

US3312201

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered '09 Feb 2021 14:16'	System	10 Feb 2021 20:51:46

US3312201

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User closed query "Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose." (Site from System).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 09:09:04
Query "Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose." answered with 'CORRECT AS ENTERED DV dose on 12JAN21 was dosed in dominant arm due to abrasion on left deltoid.' (Site from System).	Karol Moore (b) (4) (b) (4)	04 Mar 2021 21:59:21
Amendment Manager: User opened query "Treatment System Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose." (Site from System).		17 Feb 2021 01:17:32
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	10 Feb 2021 20:51:46

US3312201

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered 'ONCE'	System	10 Feb 2021 20:51:46

US3312201

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:12

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered 'INTRAMUSCULAR'	System	10 Feb 2021 20:51:46

US3312201

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:51:50

US3312201

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered 'I'	System	10 Feb 2021 20:51:50

US3312201

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:44:03

US3312201

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '16 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:44:03

US3312201

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:44:03

US3312201

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:44:03

US3312201

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:44:06

US3312201

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered 'I'	System	17 Feb 2021 15:44:06

US3312201

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:29:28

US3312201

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '10 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:29:28

US3312201

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:29:28

US3312201

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered 'OLD57'	System	11 Mar 2021 17:29:28

US3312201

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:29:36

US3312201

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:29:36

US3312201

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:29:36

US3312201

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered empty.	System	11 Mar 2021 17:29:36

US3312201

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:29:36

US3312201

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:29:36

US3312201

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:29:36

US3312201

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:29:36

US3312201

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered empty.	System	11 Mar 2021 17:29:36

US3312201

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:29:36

US3312201

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered empty.	System	11 Mar 2021 17:29:36

US3312201

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:29:36

US3312201

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered empty.	System	11 Mar 2021 17:29:36

US3312201

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:29:36

US3312201

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered empty.	System	11 Mar 2021 17:29:36

US3312201

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11

US3312201

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11

US3312201

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:16:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:32:02

US3312201

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:16:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:32:02

US3312201

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:32:20

US3312201

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '10 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:32:20

US3312201

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '13:43'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:32:20

US3312201

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:11
User entered '10 Mar 2021 13:43'	System	11 Mar 2021 17:32:20

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:16:12

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:11:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:25:14

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:16:12

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:11:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:25:14

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:16:12

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:11:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'I'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:25:14

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:16:12

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:11:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:25:14

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:16:12

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:11:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:25:14

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:11:42
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:26:00

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:11:42
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:26:00

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:11:42
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '13:40'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:26:00

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:11:42
User entered '12 Jan 2021 13:40'	System	15 Jan 2021 18:26:00

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:11:42
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User closed query 'Per CDM-Kindly consider removing unit recorded 'F' from the response field .Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 09:06:07
Query 'Per CDM-Kindly consider removing unit recorded 'F' from the response field .Thank you.' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	04 Mar 2021 17:52:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Karol Moore (b) (4) (b) (4)	04 Mar 2021 17:52:14
User opened query 'Per CDM-Kindly consider removing unit recorded 'F' from the response field .Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 08:46:15
User entered missing code ND - Not Done.	(b) (4), (b) (6)	15 Jan 2021 18:26:00

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:11:42
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:26:00

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:11:42
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:26:00

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:11:42
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:26:00

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:11:42
User entered 'bpm'	System	15 Jan 2021 18:26:00

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:11:42
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:26:00

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:11:42
User entered 'breaths/min'	System	15 Jan 2021 18:26:00

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:11:42
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '150'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:26:00

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:11:42
User entered 'mmHg'	System	15 Jan 2021 18:26:00

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:11:42
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '95'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:26:00

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:11:42
User entered 'mmHg'	System	15 Jan 2021 18:26:00

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:11:42

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:11:42

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:16:12

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:12:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:26:56

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:16:12

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:12:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:26:56

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:16:12

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:12:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'I'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:26:56

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:16:12

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:12:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:26:56

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:16:12

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:12:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:26:56

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:12:34
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:27:54

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:12:34
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:27:54

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:12:34
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '15:18'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:27:54

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:12:34
User entered '12 Jan 2021 15:18'	System	15 Jan 2021 18:27:54

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:12:34
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User closed query 'Per CDM-Kindly consider removing unit recorded 'F' from the response field .Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 09:06:14
Query 'Per CDM-Kindly consider removing unit recorded 'F' from the response field .Thank you.' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	04 Mar 2021 17:53:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Karol Moore (b) (4) (b) (4)	04 Mar 2021 17:53:28
User opened query 'Per CDM-Kindly consider removing unit recorded 'F' from the response field .Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 08:46:24
User entered missing code ND - Not Done.	(b) (4), (b) (6)	15 Jan 2021 18:27:54

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:12:34
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:27:54

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:12:34
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:27:54

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:12:34
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:27:54

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:12:34
User entered 'bpm'	System	15 Jan 2021 18:27:54

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:12:34
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:27:54

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:12:34
User entered 'breaths/min'	System	15 Jan 2021 18:27:54

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:12:34
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '159'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:27:54

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:12:34
User entered 'mmHg'	System	15 Jan 2021 18:27:54

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:12:34
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '97'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:27:54

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:12:34
User entered 'mmHg'	System	15 Jan 2021 18:27:54

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:12:34

US3312201

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:12:34

US3312201

Folder: Unscheduled 17 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:16:12

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:07:13
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '17 Sep 2020'	(b) (4)	06 Oct 2020 18:19:43
	Karol Moore (b) (4)	
	(b) (4)	

US3312201

Folder: Unscheduled 17 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:16:12

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:07:13
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:19:43

US3312201

Folder: Unscheduled 17 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:16:12

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:07:13
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'I'	(b) (4)	06 Oct 2020 18:19:43
	Karol Moore (b) (4)	
	(b) (4)	

US3312201

Folder: **Unscheduled 17 Sep 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **11 Aug 2021 22:16:12**

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:07:13
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:19:43

US3312201

Folder: Unscheduled 17 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:16:12

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:07:13
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:19:43

US3312201

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:08:17
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Yes (Y)'	(b) (4)	06 Oct 2020 18:20:03
	Karol Moore (b) (4)	
	(b) (4)	

US3312201

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:08:17
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '17 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:20:03

US3312201

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:08:17
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '14:33'	(b) (4)	06 Oct 2020 18:20:03
	Karol Moore (b) (4)	
	(b) (4)	

US3312201

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:08:17
User entered '17 Sep 2020 14:33'	System	06 Oct 2020 18:20:03

US3312201

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:08:17
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	06 Oct 2020 18:20:03

US3312201

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:08:17
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Oral (Oral)'	(b) (4)	06 Oct 2020 18:20:03
	Karol Moore (b) (4)	
	(b) (4)	

US3312201

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:08:17
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered empty.	(b) (4)	06 Oct 2020 18:20:03
	Karol Moore (b) (4)	
	(b) (4)	

US3312201

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:08:17
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	06 Oct 2020 18:20:03

US3312201

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:08:17
User entered 'bpm'	System	06 Oct 2020 18:20:03

US3312201

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:08:17
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	06 Oct 2020 18:20:03

US3312201

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:08:17
User entered 'breaths/min'	System	06 Oct 2020 18:20:03

US3312201

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:08:17
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '142'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:20:03

US3312201

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:08:17
User entered 'mmHg'	System	06 Oct 2020 18:20:03

US3312201

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:08:17
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '91'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:20:03

US3312201

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:08:17
User entered 'mmHg'	System	06 Oct 2020 18:20:03

US3312201

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:08:17

US3312201

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:08:17

US3312201

Folder: Unscheduled 20 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:16:12

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:18:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '20 Aug 2020'	(b) (4)	27 Aug 2020 16:43:41
	Karol Moore (b) (4)	
	(b) (4)	

US3312201

Folder: Unscheduled 20 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:16:12

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:18:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:43:41

US3312201

Folder: Unscheduled 20 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:16:12

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:18:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:43:41

US3312201

Folder: Unscheduled 20 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:16:12

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:18:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:43:41

US3312201

Folder: Unscheduled 20 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:16:12

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:18:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:43:41

US3312201

Folder: Unscheduled 20 Aug 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:18:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:44:06

US3312201

Folder: Unscheduled 20 Aug 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:18:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '20 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:44:06

US3312201

Folder: Unscheduled 20 Aug 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:18:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '17:00'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:44:06

US3312201

Folder: Unscheduled 20 Aug 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:18:23
User entered '20 Aug 2020 17:00'	System	27 Aug 2020 16:44:06

US3312201

Folder: Unscheduled 20 Aug 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:18:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	27 Aug 2020 16:44:06

US3312201

Folder: Unscheduled 20 Aug 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:18:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Oral (Oral)'	(b) (4)	27 Aug 2020 16:44:06
	Karol Moore (b) (4)	
	(b) (4)	

US3312201

Folder: Unscheduled 20 Aug 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:18:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered empty.	(b) (4)	27 Aug 2020 16:44:06
	Karol Moore (b) (4)	
	(b) (4)	

US3312201

Folder: Unscheduled 20 Aug 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:18:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '93'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:44:06

US3312201

Folder: Unscheduled 20 Aug 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:18:23
User entered 'bpm'	System	27 Aug 2020 16:44:06

US3312201

Folder: Unscheduled 20 Aug 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:18:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	27 Aug 2020 16:44:06

US3312201

Folder: Unscheduled 20 Aug 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:18:23
User entered 'breaths/min'	System	27 Aug 2020 16:44:06

US3312201

Folder: Unscheduled 20 Aug 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:18:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '143'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:44:06

US3312201

Folder: Unscheduled 20 Aug 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:18:23
User entered 'mmHg'	System	27 Aug 2020 16:44:06

US3312201

Folder: Unscheduled 20 Aug 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:18:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '97'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:44:06

US3312201

Folder: Unscheduled 20 Aug 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:18:23
User entered 'mmHg'	System	27 Aug 2020 16:44:06

US3312201

Folder: Unscheduled 20 Aug 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:18:23

US3312201

Folder: Unscheduled 20 Aug 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:18:23

US3312201

Folder: Unscheduled 28 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:16:12

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:18:40
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '28 Oct 2020'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:14:23

US3312201

Folder: Unscheduled 28 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:16:12

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:18:40
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '0'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:14:23

US3312201

Folder: Unscheduled 28 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:16:12

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:18:40
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'I'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:14:23

US3312201

Folder: Unscheduled 28 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:16:12

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:18:40
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '0'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:14:23

US3312201

Folder: Unscheduled 28 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:16:12

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:18:40
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	02 Nov 2020 16:14:23

US3312201

Folder: Unscheduled 28 Oct 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
	(b) (4)	
User entered 'Yes (Y)'	Monica Atwood (b) (4)	02 Nov 2020 16:14:52
	(b) (4)	

US3312201

Folder: Unscheduled 28 Oct 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '28 Oct 2020'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:14:52

US3312201

Folder: Unscheduled 28 Oct 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '12:07'	(b) (4) Monica Atwood (b) (4) (b) (4)	02 Nov 2020 16:14:52

US3312201

Folder: Unscheduled 28 Oct 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:53
User entered '28 Oct 2020 12:07'	System	02 Nov 2020 16:14:52

US3312201

Folder: Unscheduled 28 Oct 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered missing code ND - Not Done.	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:14:52

US3312201

Folder: Unscheduled 28 Oct 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered empty.	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:14:52

US3312201

Folder: Unscheduled 28 Oct 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered empty.	(b) (4) Monica Atwood (b) (4) (b) (4)	02 Nov 2020 16:14:52

US3312201

Folder: Unscheduled 28 Oct 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered missing code ND - Not Done.	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:14:52

US3312201

Folder: Unscheduled 28 Oct 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:53
User entered 'bpm'	System	02 Nov 2020 16:14:52

US3312201

Folder: Unscheduled 28 Oct 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered missing code ND - Not Done.	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:14:52

US3312201

Folder: Unscheduled 28 Oct 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:53
User entered 'breaths/min'	System	02 Nov 2020 16:14:52

US3312201

Folder: Unscheduled 28 Oct 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '174'	(b) (4) Monica Atwood (b) (4) (b) (4)	02 Nov 2020 16:14:52

US3312201

Folder: Unscheduled 28 Oct 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:53
User entered 'mmHg'	System	02 Nov 2020 16:14:52

US3312201

Folder: Unscheduled 28 Oct 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 04:07:24
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 04:07:22
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'CS, AE PAGE UPDATED' (Site from System).	Monica Atwood (b) (4) (b) (4)	02 Nov 2020 16:15:45
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'CS, AE PAGE UPDATED' (Site from System).	Monica Atwood (b) (4) (b) (4)	02 Nov 2020 16:15:34
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		02 Nov 2020 16:14:52
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		02 Nov 2020 16:14:52
User entered '115'	Monica Atwood (b) (4) (b) (4)	02 Nov 2020 16:14:52

US3312201

Folder: Unscheduled 28 Oct 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:53
User entered 'mmHg'	System	02 Nov 2020 16:14:52

US3312201

Folder: Unscheduled 28 Oct 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:53

US3312201

Folder: Unscheduled 28 Oct 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:12

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 23:18:53

US3312201

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:16:12

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:25:50
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:21:07

US3312201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:12

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Diverticulitis, LLT: Diverticulitis - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 18:23:21
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 18:23:21
	(b) (4)	
Data point term sent to Coder	System	06 Oct 2020 18:22:56
User entered 'diverticulitis'	Karol Moore (b) (4)	06 Oct 2020 18:22:02
	(b) (4)	

US3312201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	06 Oct 2020 18:22:02
	(b) (4)	

US3312201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	06 Oct 2020 18:22:02
	(b) (4)	

US3312201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	06 Oct 2020 18:22:02
	(b) (4)	

US3312201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
	(b) (4)	
User entered '24 Aug 2020'	Karol Moore (b) (4)	06 Oct 2020 18:22:02
	(b) (4)	

US3312201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Oct 2020 18:22:02
	(b) (4)	

US3312201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:12

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 18:22:02

US3312201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Monica Atwood (b) (4)	02 Nov 2020 16:23:17
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	06 Oct 2020 18:22:02
	(b) (4)	

US3312201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
	(b) (4)	
User entered '09 Oct 2020' reason for change: Data Entry Error	Monica Atwood (b) (4)	02 Nov 2020 16:23:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Oct 2020 18:22:02
	(b) (4)	

US3312201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Oct 2020 18:22:02
	(b) (4)	

US3312201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:12

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 18:22:02

US3312201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:12

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Karol Moore (b) (4)	06 Oct 2020 18:22:02
	(b) (4)	

US3312201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:12

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	06 Oct 2020 18:22:02
	(b) (4)	

US3312201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	06 Oct 2020 18:22:02
	(b) (4)	

US3312201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	06 Oct 2020 18:22:02
	(b) (4)	

US3312201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	06 Oct 2020 18:22:02
	(b) (4)	

US3312201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:12

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Oct 2020 18:22:02
	(b) (4)	

US3312201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:12

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Oct 2020 18:22:02
	(b) (4)	

US3312201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:12

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Oct 2020 18:22:02
	(b) (4)	

US3312201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:12

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Oct 2020 18:22:02
	(b) (4)	

US3312201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	06 Oct 2020 18:22:02
	(b) (4)	

US3312201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	06 Oct 2020 18:22:02
	(b) (4)	

US3312201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	06 Oct 2020 18:22:02
	(b) (4)	

US3312201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:12

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4)	06 Oct 2020 18:22:02
	(b) (4)	

US3312201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:12

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4)	06 Oct 2020 18:22:02
	(b) (4)	

US3312201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:12

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User closed query 'Per CDM: "Action taken with investigational product" is answered as "Investigational product withdrawn", however "End of Study" forms are not completed. Please consider completing "End of Study" forms or if subject withdrew only IP then please consider completing "Dosing discontinuation" form under "End of Study" folder or clarify otherwise. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:23:23
Query 'Per CDM: "Action taken with investigational product" is answered as "Investigational product withdrawn", however "End of Study" forms are not completed. Please consider completing "End of Study" forms or if subject withdrew only IP then please consider completing "Dosing discontinuation" form under "End of Study" folder or clarify otherwise. Thank you.' answered with 'DOSING DISCONTINUATION PAGE UPDATED' (Site from DM).	Monica Atwood (b) (4) (b) (4)	13 Nov 2020 17:57:47
User opened query 'Per CDM: "Action taken with investigational product" is answered as "Investigational product withdrawn", however "End of Study" forms are not completed. Please consider completing "End of Study" forms or if subject withdrew only IP then please consider completing "Dosing discontinuation" form under "End of Study" folder or clarify otherwise. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 15:27:24
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:22:02

US3312201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:12

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	06 Oct 2020 18:22:02
	(b) (4)	

US3312201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:12

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
	(b) (4)	
User entered 'I'	Karol Moore (b) (4)	06 Oct 2020 18:22:02
	(b) (4)	

US3312201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:12

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	06 Oct 2020 18:22:02
	(b) (4)	

US3312201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:12

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Monica Atwood (b) (4)	02 Nov 2020 16:23:17
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Karol Moore (b) (4)	06 Oct 2020 18:22:02
	(b) (4)	

US3312201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:12

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Oct 2020 18:22:02
	(b) (4)	

US3312201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:12

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Oct 2020 18:22:02
	(b) (4)	

US3312201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:12

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Oct 2020 18:22:02

US3312201

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:12

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 18:22:02

US3312201

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:12

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:39

US3312201

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:12

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:39
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User coded data point as SOC: Gastrointestinal disorders, HLGT: Benign neoplasms gastrointestinal, HLT: Benign neoplasms gastrointestinal (excl oral cavity), PT: Large intestine polyp, LLT: Colonic polyp - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 22:00:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 22:00:22
Data point term sent to Coder	System	02 Nov 2020 16:22:54
User entered 'COLONIC POLYP'	Monica Atwood (b) (4)	02 Nov 2020 16:22:35

US3312201

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:39
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:22:35

US3312201

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:39
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:22:35

US3312201

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:39
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:22:35

US3312201

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:39
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '09 Oct 2020'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:22:35

US3312201

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:39
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered empty.	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:22:35

US3312201

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:12

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:39
User entered empty.	System	02 Nov 2020 16:22:35

US3312201

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:39
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:22:35

US3312201

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:12

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:39
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '09 Oct 2020'	(b) (4) Monica Atwood (b) (4) (b) (4)	02 Nov 2020 16:22:35

US3312201

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:39
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered empty.	(b) (4) Monica Atwood (b) (4) (b) (4)	02 Nov 2020 16:22:35

US3312201

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:12

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:39
User entered empty.	System	02 Nov 2020 16:22:35

US3312201

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:12

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:39
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:22:35
	(b) (4)	

US3312201

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:12

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:39
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:22:35

US3312201

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:12

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:39
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	02 Nov 2020 16:22:35

US3312201

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:12

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:39
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '0'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:22:35

US3312201

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:39
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '0'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:22:35

US3312201

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:12

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:39
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered empty.	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:22:35

US3312201

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:12

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:39
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered empty.	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:22:35

US3312201

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:12

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:39
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered empty.	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:22:35

US3312201

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:12

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:39
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered empty.	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:22:35

US3312201

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:39
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '0'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:22:35

US3312201

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:39
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '0'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:22:35

US3312201

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:12

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:39
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '0'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:22:35

US3312201

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:12

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:39
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'Not Related (NOT RELATED)'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:22:35

US3312201

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:12

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:39
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'Not Related (NOT RELATED)'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:22:35

US3312201

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:12

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:39
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'None (NONE)'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:22:35

US3312201

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:12

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:39
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '0'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:22:35

US3312201

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:12

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:39
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '0'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:22:35

US3312201

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:12

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:39
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'I'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:22:35

US3312201

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:12

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:39
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:22:35

US3312201

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:12

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:39
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered empty.	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:22:35

US3312201

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:12

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:39
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered empty.	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:22:35

US3312201

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:12

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:39
User entered '0'	System	02 Nov 2020 16:22:35

US3312201

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:12

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:39
User entered 'I'	System	02 Nov 2020 16:22:35

US3312201

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:12

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:39

US3312201

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:16:12

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:44

US3312201

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:16:12

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:44
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User coded data point as SOC: Investigations, HLG: Cardiac and vascular investigations (excl enzyme tests), HLT: Vascular tests NEC (incl blood pressure), PT: Blood pressure systolic increased, LLT: Blood pressure systolic increased - version MedDRA\23.0.	Coder Import (b) (4)	04 Nov 2020 22:28:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Nov 2020 22:28:17
Data point term sent to Coder	System	02 Nov 2020 16:25:58
User entered 'ELEVATED SYSTOLIC BLOOD PRESSURE'	Monica Atwood (b) (4)	02 Nov 2020 16:25:04

US3312201

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:16:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:44
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:25:04

US3312201

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:16:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:44
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:25:04

US3312201

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:16:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:44
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:25:04

US3312201

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:44
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '28 Oct 2020'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:25:04

US3312201

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:44
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered empty.	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:25:04

US3312201

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:16:12

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:44
User entered empty.	System	02 Nov 2020 16:25:04

US3312201

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:16:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:44
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	06 Mar 2021 17:11:05
User entered 'Yes (Y)'	Karol Moore (b) (4)	02 Nov 2020 16:25:04
	(b) (4)	

US3312201

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:16:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:44
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	06 Mar 2021 17:11:13
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	06 Mar 2021 17:11:13
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	06 Mar 2021 17:11:05
User entered '28 Jan 2021' reason for change: Data Entry Error	Karol Moore (b) (4)	06 Mar 2021 17:11:05
User entered empty.	(b) (4)	02 Nov 2020 16:25:04
	Monica Atwood (b) (4)	
	(b) (4)	

US3312201

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:44
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered empty.	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:25:04

US3312201

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:16:12

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:44
User entered empty.	System	02 Nov 2020 16:25:04

US3312201

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:16:12

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:44
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:25:04

US3312201

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:16:12

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:44
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:25:04

US3312201

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:16:12

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:44
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	02 Nov 2020 16:25:04

US3312201

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:16:12

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:44
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '0'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:25:04

US3312201

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:16:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:44
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '0'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:25:04

US3312201

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:16:12

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:44
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered empty.	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:25:04

US3312201

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:16:12

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:44
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered empty.	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:25:04

US3312201

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:16:12

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:44
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered empty.	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:25:04

US3312201

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:16:12

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:44
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered empty.	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:25:04

US3312201

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:16:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:44
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '0'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:25:04

US3312201

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:16:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:44
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '0'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:25:04

US3312201

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:16:12

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:44
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	02 Nov 2020 16:25:04

US3312201

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:16:12

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:44
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'Not Related (NOT RELATED)'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:25:04

US3312201

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:16:12

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:44
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'Not Related (NOT RELATED)'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:25:04

US3312201

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:16:12

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:44
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'None (NONE)'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:25:04

US3312201

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:16:12

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:44
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'I'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:25:04

US3312201

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:16:12

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:44
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '0'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:25:04

US3312201

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:16:12

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:44
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '0'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:25:04

US3312201

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:16:12

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:44
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Karol Moore (b) (4)	06 Mar 2021 17:11:13
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4)	
	Monica Atwood (b) (4)	02 Nov 2020 16:25:04
	(b) (4)	

US3312201

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:16:12

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:44
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered empty.	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:25:04

US3312201

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:16:12

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:44
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered empty.	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:25:04

US3312201

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:16:12

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:44
User entered '0'	System	02 Nov 2020 16:25:04

US3312201

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:16:12

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:44
User entered '0'	System	02 Nov 2020 16:25:04

US3312201

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:16:12

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:44

US3312201

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:16:12

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:46

US3312201

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:16:12

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User coded data point as SOC: Investigations, HLG: Cardiac and vascular investigations (excl enzyme tests), HLT: Vascular tests NEC (incl blood pressure), PT: Blood pressure diastolic increased, LLT: Diastolic blood pressure increased - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 22:35:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 22:35:01
Data point term sent to Coder	System	02 Nov 2020 16:27:00
User entered 'ELEVATED DIASTOLIC BLOOD PRESSURE'	Monica Atwood (b) (4)	02 Nov 2020 16:26:03

US3312201

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:16:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:26:03

US3312201

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:16:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:26:03

US3312201

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:16:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:26:03

US3312201

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '28 Oct 2020'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:26:03

US3312201

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered empty.	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:26:03

US3312201

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:16:12

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:46
User entered empty.	System	02 Nov 2020 16:26:03

US3312201

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:16:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	06 Mar 2021 17:11:32
User entered 'Yes (Y)'	Karol Moore (b) (4)	02 Nov 2020 16:26:03
	(b) (4)	

US3312201

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:16:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '28 Jan 2021' reason for change: Data Entry Error	(b) (4)	06 Mar 2021 17:11:32
User entered empty.	Karol Moore (b) (4)	02 Nov 2020 16:26:03
	(b) (4)	

US3312201

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered empty.	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:26:03

US3312201

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:16:12

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:46
User entered empty.	System	02 Nov 2020 16:26:03

US3312201

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:16:12

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:26:03

US3312201

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:16:12

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:26:03

US3312201

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:16:12

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	02 Nov 2020 16:26:03

US3312201

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:16:12

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '0'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:26:03

US3312201

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:16:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '0'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:26:03

US3312201

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:16:12

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered empty.	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:26:03

US3312201

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:16:12

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered empty.	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:26:03

US3312201

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:16:12

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered empty.	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:26:03

US3312201

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:16:12

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered empty.	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:26:03

US3312201

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:16:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '0'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:26:03

US3312201

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:16:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '0'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:26:03

US3312201

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:16:12

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	02 Nov 2020 16:26:03

US3312201

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:16:12

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'Not Related (NOT RELATED)'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:26:03

US3312201

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:16:12

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'Not Related (NOT RELATED)'	(b) (4) Monica Atwood (b) (4) (b) (4)	02 Nov 2020 16:26:03

US3312201

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:16:12

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'None (NONE)'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:26:03

US3312201

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:16:12

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'I'	(b) (4) Monica Atwood (b) (4) (b) (4)	02 Nov 2020 16:26:03

US3312201

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:16:12

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '0'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:26:03

US3312201

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:16:12

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '0'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:26:03

US3312201

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:16:12

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Karol Moore (b) (4)	06 Mar 2021 17:11:32
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4)	
	Monica Atwood (b) (4)	02 Nov 2020 16:26:03
	(b) (4)	

US3312201

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:16:12

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered empty.	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:26:03

US3312201

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:16:12

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered empty.	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:26:03

US3312201

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:16:12

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:46
User entered '0'	System	02 Nov 2020 16:26:03

US3312201

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:16:12

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:46
User entered '0'	System	02 Nov 2020 16:26:03

US3312201

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:16:12

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:46

US3312201

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:16:12

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:50

US3312201

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:16:12

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:50
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Skin injuries NEC, PT: Skin abrasion, LLT: Abrasion - version MedDRA\\23.0.	Coder Import (b) (4)	16 Jan 2021 10:37:08
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	16 Jan 2021 10:37:08
Data point term sent to Coder	System	15 Jan 2021 18:49:34
User entered 'Abrasion Left Deltoid'	(b) (4), (b) (6)	15 Jan 2021 18:48:42

US3312201

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:16:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:50
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:48:42

US3312201

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:16:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:50
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:48:42

US3312201

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:16:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:50
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:48:42

US3312201

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:50
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '10 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:48:42

US3312201

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:50
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:48:42

US3312201

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:16:12

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:50
User entered empty.	System	15 Jan 2021 18:48:42

US3312201

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:16:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:50
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	23 Feb 2021 20:37:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Jan 2021 18:48:42

US3312201

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:16:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:50
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '19 Jan 2021' reason for change: Data Entry Error	(b) (4)	23 Feb 2021 20:37:23
User entered empty.	Monica Atwood (b) (4)	15 Jan 2021 18:48:42
	(b) (4)	
	(b) (4), (b) (6)	

US3312201

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:50
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:48:42

US3312201

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:16:12

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:50
User entered empty.	System	15 Jan 2021 18:48:42

US3312201

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:16:12

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:50
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:48:42

US3312201

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:16:12

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:50
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:48:42

US3312201

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:16:12

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:50
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:48:42

US3312201

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:16:12

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:50
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:48:42

US3312201

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:16:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:50
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:48:42

US3312201

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:16:12

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:50
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:48:42

US3312201

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:16:12

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:50
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:48:42

US3312201

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:16:12

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:50
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:48:42

US3312201

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:16:12

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:50
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:48:42

US3312201

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:16:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:50
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:48:42

US3312201

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:16:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:50
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:48:42

US3312201

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:16:12

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:50
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:48:42

US3312201

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:16:12

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:50
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:48:42

US3312201

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:16:12

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:50
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:48:42

US3312201

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:16:12

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:50
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:48:42

US3312201

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:16:12

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:50
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'I'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:48:42

US3312201

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:16:12

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:50
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:48:42

US3312201

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:16:12

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:50
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:48:42

US3312201

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:16:12

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:50
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Monica Atwood (b) (4)	23 Feb 2021 20:37:23
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	15 Jan 2021 18:48:42

US3312201

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:16:12

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:50
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:48:42

US3312201

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:16:12

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:50
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:55
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:48:42

US3312201

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:16:12

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:50
User entered '0'	System	15 Jan 2021 18:48:42

US3312201

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:16:12

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:50
User entered '0'	System	15 Jan 2021 18:48:42

US3312201

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:16:12

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:26:50

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:16:12

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:25:50
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:39:31

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:16:12

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	27 Aug 2020 20:39:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 20:39:53
Data point term sent to Coder	System	27 Aug 2020 16:41:04
User entered 'HYDROCODONE'	Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:40:09

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:16:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	27 Aug 2020 16:40:09
	(b) (4)	

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:16:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
	(b) (4)	
User entered 'L2-L5 HERNIATED DISC'	Karol Moore (b) (4)	27 Aug 2020 16:40:09
	(b) (4)	

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:16:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
	(b) (4)	
User entered '10'	Karol Moore (b) (4)	27 Aug 2020 16:40:09
	(b) (4)	

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:16:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	27 Aug 2020 16:40:09
	(b) (4)	

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:16:12

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	27 Aug 2020 16:40:09
	(b) (4)	

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:16:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
	(b) (4)	
User entered 'twice daily (BID)'	Karol Moore (b) (4)	27 Aug 2020 16:40:09
	(b) (4)	

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:16:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	27 Aug 2020 16:40:09
	(b) (4)	

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:16:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	27 Aug 2020 16:40:09
	(b) (4)	

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:16:12

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	27 Aug 2020 16:40:09
	(b) (4)	

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
	(b) (4)	
User entered 'UN UNK 2010'	Karol Moore (b) (4)	27 Aug 2020 16:40:09
	(b) (4)	

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:16:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	27 Aug 2020 16:40:09
	(b) (4)	

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:16:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	27 Aug 2020 16:40:09
	(b) (4)	

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:16:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	27 Aug 2020 16:40:09
	(b) (4)	

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:16:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	27 Aug 2020 16:40:09
	(b) (4)	

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:16:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	27 Aug 2020 16:40:09

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:16:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 16:40:09

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:16:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 16:40:09

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:16:12

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Sep 2020 11:43:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Sep 2020 11:43:40
Data point term sent to Coder	System	27 Aug 2020 16:41:04
User entered 'OXYCODONE'	Karol Moore (b) (4) (b) (4)	27 Aug 2020 16:40:57

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:16:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	27 Aug 2020 16:40:57
	(b) (4)	

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:16:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
	(b) (4)	
User entered 'L2-L5 HERNIATED LUMBAR DISC'	Karol Moore (b) (4)	27 Aug 2020 16:40:57
	(b) (4)	

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:16:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
	(b) (4)	
User entered '10'	Karol Moore (b) (4)	27 Aug 2020 16:40:57
	(b) (4)	

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:16:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	27 Aug 2020 16:40:57
	(b) (4)	

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:16:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	27 Aug 2020 16:40:57
	(b) (4)	

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:16:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
	(b) (4)	
User entered 'three times daily (TID)'	Karol Moore (b) (4)	27 Aug 2020 16:40:57
	(b) (4)	

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:16:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	27 Aug 2020 16:40:57
	(b) (4)	

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:16:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	27 Aug 2020 16:40:57
	(b) (4)	

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:16:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	27 Aug 2020 16:40:57
	(b) (4)	

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
	(b) (4)	
User entered 'UN Mar 2020'	Karol Moore (b) (4)	27 Aug 2020 16:40:57
	(b) (4)	

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:16:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	27 Aug 2020 16:40:57
	(b) (4)	

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:16:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	27 Aug 2020 16:40:57
	(b) (4)	

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:16:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	27 Aug 2020 16:40:57
	(b) (4)	

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:16:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	27 Aug 2020 16:40:57
	(b) (4)	

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:16:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	27 Aug 2020 16:40:57

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:16:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 16:40:57

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:16:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 16:40:57

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:16:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Oct 2020 12:36:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 12:36:47
Data point term sent to Coder	System	06 Oct 2020 18:21:54
User entered 'ciprofloxacin'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:20:55

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:16:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:20:55

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:16:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'diverticullitis'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:20:55

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:16:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '500'	Karol Moore (b) (4)	06 Oct 2020 18:20:55

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:16:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:20:55

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:16:12

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:20:55

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:16:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'twice daily (BID)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:20:55

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:16:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:20:55

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:16:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Oral (ORAL)'	(b) (4)	06 Oct 2020 18:20:55
	Karol Moore (b) (4)	
	(b) (4)	

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:16:12

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:20:55

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '28 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:20:55

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:16:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:20:55

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:16:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:20:55

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:16:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '06 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:20:55

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:16:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:20:55

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:16:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:53
User entered '2'	System	06 Oct 2020 18:20:55

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:16:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:53
User entered '1'	System	06 Oct 2020 18:20:55

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:16:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:53
User entered '804 (804)'	System	06 Oct 2020 18:20:55

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:16:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:56
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PRODUCT: CORTICOSTEROID NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 09:39:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 09:39:05
Data point term sent to Coder	System	09 Apr 2021 13:41:06
User closed query 'Per CDM Coding: Please update the term TRANSFORAMINAL EPIDURAL STEROID INJECTION with the brand or active ingredient name(s) or type of medication.' (Site from System).	System	09 Apr 2021 13:40:47
Query 'Per CDM Coding: Please update the term TRANSFORAMINAL EPIDURAL STEROID INJECTION with the brand or active ingredient name(s) or type of medication.' answered with 'ACTIVE INGREDIENT UNKNOWN.' (Site from System).	(b) (4), (b) (6)	09 Apr 2021 13:40:47
User opened query 'Per CDM Coding: Please update the term TRANSFORAMINAL EPIDURAL STEROID INJECTION with the brand or active ingredient name(s) or type of medication.' (Site from System).	Coder Import (b) (4) (b) (4)	08 Apr 2021 10:35:36
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	06 Apr 2021 21:33:00
Data point term sent to Coder	System	06 Apr 2021 19:56:12
User entered 'Transforaminal epidural steroid injection'	Kelly Moen (b) (4) (b) (4)	06 Apr 2021 19:56:09

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:16:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:56
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 21:33:00
User entered 'No (N)'	(b) (4) Kelly Moen (b) (4) (b) (4)	06 Apr 2021 19:56:09

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:16:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:56
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 21:33:00
User entered 'back pain'	(b) (4) Kelly Moen (b) (4) (b) (4)	06 Apr 2021 19:56:09

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:16:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:56
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 21:33:00
User entered 'I'	(b) (4) Kelly Moen (b) (4) (b) (4)	06 Apr 2021 19:56:09

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:16:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:56
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 21:33:00
User entered 'Other (OTHER)'	(b) (4) Kelly Moen (b) (4) (b) (4)	06 Apr 2021 19:56:09

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:16:12

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:56
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 21:33:00
User entered 'injection'	(b) (4) Kelly Moen (b) (4) (b) (4)	06 Apr 2021 19:56:09

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:16:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:56
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 21:33:00
User entered 'once (ONCE)'	(b) (4) Kelly Moen (b) (4) (b) (4)	06 Apr 2021 19:56:09

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:16:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:56
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 21:33:00
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	06 Apr 2021 19:56:09

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:16:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:56
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 21:33:00
User entered 'Other (OTHER)'	(b) (4) Kelly Moen (b) (4) (b) (4)	06 Apr 2021 19:56:09

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:16:12

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:56
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 21:33:00
User entered 'intra-articular'	(b) (4) Kelly Moen (b) (4) (b) (4)	06 Apr 2021 19:56:09

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:56
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 21:33:00
User entered '11 Mar 2021'	(b) (4) Kelly Moen (b) (4) (b) (4)	06 Apr 2021 19:56:09

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:16:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:56
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 21:33:00
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	06 Apr 2021 19:56:09

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:16:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:56
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 21:33:00
User entered 'No (N)'	(b) (4) Kelly Moen (b) (4) (b) (4)	06 Apr 2021 19:56:09

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:16:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:56
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 21:33:00
User entered '11 Mar 2021'	(b) (4) Kelly Moen (b) (4) (b) (4)	06 Apr 2021 19:56:09

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:16:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:56
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 21:33:00
User entered 'No (N)'	(b) (4) Kelly Moen (b) (4) (b) (4)	06 Apr 2021 19:56:09

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:16:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:56
User entered empty.	System	06 Apr 2021 19:56:09

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:16:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:56
User entered empty.	System	06 Apr 2021 19:56:09

US3312201

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:16:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:56
User entered empty.	System	06 Apr 2021 19:56:09

US3312201

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:16:12

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:25:50
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4)	02 Nov 2020 16:18:47

US3312201

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:16:12

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
	(b) (4)	
User entered '9 Oct 2020'	Monica Atwood (b) (4)	02 Nov 2020 16:19:24
	(b) (4)	

US3312201

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:16:12

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
	(b) (4)	
User entered 'POLYPECTOMY'	Monica Atwood (b) (4)	02 Nov 2020 16:19:24
	(b) (4)	

US3312201

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:16:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
	(b) (4)	
User entered 'Adverse Event (AE)'	Monica Atwood (b) (4)	02 Nov 2020 16:19:24
	(b) (4)	

US3312201

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:16:12

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
	(b) (4)	
User entered empty.	Monica Atwood (b) (4)	02 Nov 2020 16:19:24
	(b) (4)	

US3312201

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:16:12

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:51:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User entered '17 Sep 2020'	(b) (4) Monica Atwood (b) (4)	13 Nov 2020 17:57:09

US3312201

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:16:12

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:51:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
Query 'Per CDM: Primary reason for dosing discontinuation is recorded as 'Due to AE', However, no data is recorded on 'End of Study / Study Discontinuation' form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 12:21:34
User opened query 'Per CDM: Primary reason for dosing discontinuation is recorded as 'Due to AE', However, no data is recorded on 'End of Study / Study Discontinuation' form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 11:10:53
User entered 'AE (specify) (ADVERSE EVENT)'	Monica Atwood (b) (4) (b) (4)	13 Nov 2020 17:57:09

US3312201

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:16:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:51:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:16:15
User closed query 'Per CDM Re-query: thank you for teh update however per CCGs, please remove the details' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 08:40:17
Query 'Per CDM Re-query: thank you for teh update however per CCGs, please remove the details' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	23 Nov 2020 18:34:22
User entered 'AE#1' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	23 Nov 2020 18:34:18
User opened query 'Per CDM Re-query: thank you for teh update however per CCGs, please remove the details' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 22:38:19
User closed query 'Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 22:38:19
Query 'Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details' answered with 'updated' (Site from DM).	Monica Atwood (b) (4) (b) (4)	20 Nov 2020 21:01:34
User entered 'AE#1-DIVERTICULITIS' reason for change: Data Entry Error	Monica Atwood (b) (4) (b) (4)	20 Nov 2020 21:01:15
User opened query 'Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 14:57:12
User entered 'DIVERTICULITIS'	Monica Atwood (b) (4) (b) (4)	13 Nov 2020 17:57:09