

US3312587 (Prod: Johnson County Clin-Trials)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:12:54

All time stamps listed in this document are displayed in GMT

US3312587

Form: Participant Creation

Data signed: (b) (4) 07 Apr 2021 19:13:37

Generated On: 11 Aug 2021 22:12:54

[Participant ID](#)

US3312587

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

US3312587

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3312587

Folder: Screening

Form: Demographics

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

Date of Birth (MMM yyyy)	(b) (6) 1993
Age	27
Age Units	YEARS
Age (Derived)	27
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3312587

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

Date of Informed Consent (<i>dd MMM yyyy</i>)	09 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" 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

US3312587

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3312587

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

Were any significant conditions reported?

Yes ☒

No ☐

US3312587

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

Condition	OCCASIONAL MIGRAINE
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Start Year (derived)	2003
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3312587

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

Condition	RIGHT CARPAL TUNNEL
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)	

US3312587

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

US3312587

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3312587

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

Condition	UNILATERAL SALPINGECTOMY
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

US3312587

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

Condition	CYST ON FALLOPIAN TUBE
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

US3312587

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3312587

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

Condition	ATTENTION DEFICIT HYPERACTIVITY DISORDER
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

US3312587

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	09 SEP 2020
Time of assessment (00:00-23:59)	15:53 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 15:53
Height (xxx.x)	67 in
Weight (xxx.x)	166 lb
BMI (xxx.x)	26.05364 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)	

US3312587

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 SEP 2020

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

US3312587

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

Date of assessment (dd MMM yyyy) 09 SEP 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

If Partner medically sterile or Other, specify _____
If Surgically sterile, date of surgery (dd MMM yyyy) _____
Date of surgery unknown False
If Post-menopausal, date of last menstruation (dd MMM yyyy) _____
Date of last menstruation unknown False

US3312587

Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	09 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3312587

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

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

US3312587

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

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

US3312587

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3312587

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

What was the date of randomization? (dd MMM yyyy) 09 SEP 2020

What was the participant's randomization number? 112905

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 ☒

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

Height	ND - Not Done
Weight	ND - Not Done

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

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)	09 SEP 2020
Time of assessment (00:00-23:59)	15:53 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 15:53
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)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

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)	09 SEP 2020
Time of assessment (00:00-23:59)	17:26 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 17:26
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3312587

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

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.

US3312587

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☐

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3312587

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

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) 09 SEP 2020

What was the treatment time? (00:00-23:59) 16:55 (24 HR)

Treatment Date and Time (derived) 09 SEP 2020 16:55

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

US3312587

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

09 SEP 2020

Collection time (00:00-23:59)

16:25 (24 HR)

Collection date and time (derived)

09 SEP 2020 16:25

US3312587

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

Collection date (dd MMM yyyy)			09 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:21	09 SEP 2020 16:21
Nasopharyngeal Swab 2	No		

US3312587

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 17:25

PC Open Date & Time

09 SEP 2020 17:15

PC Close Date & Time

09 SEP 2020 19:45

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:12:54

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 98.6 °F

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

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

PC Time Stamp	09 SEP 2020 21:42
PC Open Date & Time	09 SEP 2020 20:40
PC Close Date & Time	10 SEP 2020 11:59

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:12:54

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

97.3 °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

10 SEP 2020 23:23

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:12:54

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

97.4 °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

11 SEP 2020 20:44

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:12:54

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

96.4 °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

12 SEP 2020 20:57

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:12:54

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 10:01

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 22:51

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 21:44

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 17:25

PC Open Date & Time

09 SEP 2020 17:15

PC Close Date & Time

09 SEP 2020 19:45

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:12:54

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

09 SEP 2020 21:14

PC Open Date & Time

09 SEP 2020 20:40

PC Close Date & Time

10 SEP 2020 11:59

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:12:54

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

10 SEP 2020 23:20

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:12:54

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

11 SEP 2020 20:45

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:12:54

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

12 SEP 2020 20:56

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 09:58

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:12:54

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

14 SEP 2020 22:51

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:12:54

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

15 SEP 2020 21:44

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:54

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 ☐

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:54

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 17:26
PC Open Date & Time	09 SEP 2020 17:15
PC Close Date & Time	09 SEP 2020 19:45

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:54

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 ☐

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:54

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 21:15
PC Open Date & Time	09 SEP 2020 20:40
PC Close Date & Time	10 SEP 2020 11:59

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:12:54

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 ☒

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:12:54

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 23:20
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:12:54

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 ☒

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:12:54

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 20:45
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:12:54

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 ☒

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:12:54

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 20:56
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:12:54

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 ☒

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:12:54

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 09:58
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:12:54

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 ☒

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:12:54

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 22:50
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:12:54

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 ☒

PRODUCTION RELEASE (v12.003

62 of 2566

EAB) (1725)

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:12:54

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 21:44
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3312587

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312587

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312587

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312587

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312587

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312587

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312587

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 20:59:47

Generated On: 11 Aug 2021 22:12:54

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT2

US3312587

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 20:59:47

Generated On: 11 Aug 2021 22:12:54

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

US3312587

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 20:59:47

Generated On: 11 Aug 2021 22:12:54

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

US3312587

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

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.

US3312587

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☐

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3312587

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

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?

US3312587

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3312587

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

Collection date (*dd MMM yyyy*)

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

US3312587

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312587

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

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

OCCURRED DURING
CONVALESCENT PERIOD.

If Contact Not Made, please provide Comments

US3312587

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312587

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

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

OCCURRED DURING
CONVALESCENT PERIOD.

If Contact Not Made, please provide Comments

US3312587

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312587

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

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

OCCURRED DURING
CONVALESCENT PERIOD.

If Contact Not Made, please provide Comments

US3312587

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 20:59:42

Generated On: 11 Aug 2021 22:12:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312587

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 20:59:47

Generated On: 11 Aug 2021 22:12:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 NOV 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

US3312587

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 20:59:47

Generated On: 11 Aug 2021 22:12:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	06 NOV 2020
Time of assessment (00:00-23:59)	14:13 (24 HR)
Vital Signs Date and Time (derived)	06 NOV 2020 14:13
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)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312587

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 20:59:47

Generated On: 11 Aug 2021 22:12:54

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.

US3312587

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 20:59:47

Generated On: 11 Aug 2021 22:12:54

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

06 NOV 2020

Collection time (00:00-23:59)

14:24 (24 HR)

Collection date and time (derived)

06 NOV 2020 14:24

US3312587

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 20:59:47

Generated On: 11 Aug 2021 22:12:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312587

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 12:00:56

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3312587

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

16 NOV 2020 00:02:09

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 19:44:04
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 NOV 2020 12:00:23
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

DAY 89

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

No ☒

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

06 DEC 2020 12:09:46

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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 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	14 DEC 2020 14:32:43
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 DEC 2020 12:19:55

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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	25 DEC 2020 02:43:35
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 JAN 2021 09:25:30

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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	10 JAN 2021 12:00:47
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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	18 JAN 2021 15:22:02
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

24 JAN 2021 12:00:55

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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 ☒

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

31 JAN 2021 12:11:13

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

05 FEB 2021 09:20:46

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

14 FEB 2021 12:00:29

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 FEB 2021 16:39:27

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAR 2021 17:59:43

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 12:00:54

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

14 MAR 2021 12:30:21

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 MAR 2021 12:02:20
Patient Cloud Open Date & Time	19 MAR 2021 00:01
Patient Cloud Close Date & Time	23 MAR 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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	28 MAR 2021 12:00:39
Patient Cloud Open Date & Time	26 MAR 2021 00:01
Patient Cloud Close Date & Time	30 MAR 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

04 APR 2021 12:37:53

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

11 APR 2021 12:03:52

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 APR 2021 17:59:22

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 12:00:52

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

30 APR 2021 13:03:22

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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"/>

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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 ☐ 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 ☐

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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 ☐

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

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 ☐

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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 ☐ 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 ☐

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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 ☐

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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°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 ☐

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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 ☐

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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 ☐

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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"/>

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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°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 ☐

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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"/>

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	05 OCT 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

DAY 397

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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°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 ☐

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	19 OCT 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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"/>

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	22 OCT 2021 00:01
Patient Cloud Close Date & Time	26 OCT 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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"/>

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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°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 ☐

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	21 DEC 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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"/>

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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 ☐

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

DAY 537

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

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

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

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

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

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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°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 ☐

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT	DAY 551
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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°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 ☐

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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 ☐

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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 ☐

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

DAY 579

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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 ☐

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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"/>

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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 ☐

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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 ☐

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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 ☐

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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°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 ☐

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

DAY 663

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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 ☐

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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"/>

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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"/>

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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"/>

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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"/>

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	14 OCT 2022 00:01
Patient Cloud Close Date & Time	18 OCT 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

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 ☐

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

21 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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 ☐

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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 ☐ 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 ☐

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

[Patient Cloud Close Date & Time](#)

15 NOV 2022 23:59

US3312587

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:12:54

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 17:59:56

US3312587

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 19:14:00

Generated On: 11 Aug 2021 22:12:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312587

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 19:14:00

Generated On: 11 Aug 2021 22:12:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312587

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 19:14:00

Generated On: 11 Aug 2021 22:12:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312587

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 19:14:00

Generated On: 11 Aug 2021 22:12:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312587

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 19:14:00

Generated On: 11 Aug 2021 22:12:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312587

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 19:14:00

Generated On: 11 Aug 2021 22:12:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312587

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 19:14:00

Generated On: 11 Aug 2021 22:12:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312587

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 19:14:00

Generated On: 11 Aug 2021 22:12:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312587

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 19:14:01

Generated On: 11 Aug 2021 22:12:54

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

Visit date (dd MMM yyyy)	06 APR 2021
--------------------------	-------------

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

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

US3312587

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 19:14:25

Generated On: 11 Aug 2021 22:12:54

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) _____

US3312587

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 19:14:01

Generated On: 11 Aug 2021 22:12:54

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.

US3312587

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 19:14:01

Generated On: 11 Aug 2021 22:12:54

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

06 APR 2021

Collection time (00:00-23:59)

13:34 (24 HR)

Collection date and time (derived)

06 APR 2021 13:34

US3312587

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 19:14:01

Generated On: 11 Aug 2021 22:12:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312587

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

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

US3312587

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:54

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 07 Apr 2021 19:13:58

Generated On: 11 Aug 2021 22:12:54

Date of Contact	07 OCT 2020
Time of Contact	10:00
Date and Time of Contact (derived)	07 OCT 2020 10:00
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	03 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	04 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	05 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

302 of 2566

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	06 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	100.6 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

306 of 2566

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	07 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

310 of 2566

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	08 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

314 of 2566

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	09 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

318 of 2566

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

322 of 2566

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

326 of 2566

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input checked="" type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

330 of 2566

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input checked="" type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 OCT 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

334 of 2566

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

335 of 2566

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input checked="" type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

338 of 2566

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input checked="" type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	15 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	96 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.1 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

342 of 2566

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

343 of 2566

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input checked="" type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 OCT 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

346 of 2566

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input checked="" type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 OCT 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

350 of 2566

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

351 of 2566

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input checked="" type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	96.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

354 of 2566

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input checked="" type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	96.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

358 of 2566

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

359 of 2566

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input checked="" type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 OCT 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	96.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

362 of 2566

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 07 Apr 2021 19:13:37

Generated On: 11 Aug 2021 22:12:54

Date of Visit	07 OCT 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	07 OCT 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 07 Apr 2021 19:13:58

Generated On: 11 Aug 2021 22:12:54

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date _____

PRODUCTION RELEASE (v12.003

EAB) (1725)

366 of 2566

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 07 Apr 2021 19:13:58

Generated On: 11 Aug 2021 22:12:54

If Yes to either Did subject require any of the following:

Ventilator Support:

High-Flow Oxygen?

Yes ☐

No ☒

Start Date

End Date

Non-Invasive Ventilation?

Yes ☐

No ☒

Start Date

End Date

Mechanical Ventilation?

Yes ☐

No ☒

Start Date

End Date

ECMO?

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors

Yes ☐

No ☒

Start Date

End Date

Acute Renal Dysfunction?

Yes ☐

No ☒

Start Date

PRODUCTION RELEASE (v12.003

EAB) (1725)

367 of 2566

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 07 Apr 2021 19:13:58

Generated On: 11 Aug 2021 22:12:54

Hepatic Dysfunction? Yes ☐ No ☒

Start Date

Neurologic Dysfunction? Yes ☐ No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐ No ☒

Date of Assessment

Radiographical Evidence Yes ☐ No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐ No ☒

Start Date

End Date

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 07 Apr 2021 19:13:58

Generated On: 11 Aug 2021 22:12:54

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3312587

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	09 OCT 2020
Day 5	Yes	11 OCT 2020
Day 7	Yes	13 OCT 2020
Day 9	Yes	15 OCT 2020
Day 14	Yes	21 OCT 2020
Day 21	Yes	28 OCT 2020
Day 28	Yes	03 NOV 2020

US3312587

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 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	SICKD1

US3312587

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 19:14:00

Generated On: 11 Aug 2021 22:12:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 OCT 2020
Time of assessment (00:00-23:59)	13:35 (24 HR)
Vital Signs Date and Time (derived)	07 OCT 2020 13:35
Height (xxx.x)	67 in
Weight (xxx.x)	159.5 lb
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312587

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 OCT 2020

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

US3312587

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

07 OCT 2020

US3312587

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 19:13:37

Generated On: 11 Aug 2021 22:12:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3312587

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 19:13:37

Generated On: 11 Aug 2021 22:12:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 NOV 2020
Time of assessment (00:00-23:59)	10:46 (24 HR)
Vital Signs Date and Time (derived)	03 NOV 2020 10:46
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312587

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 19:13:37

Generated On: 11 Aug 2021 22:12:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 NOV 2020

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

US3312587

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 07 Apr 2021 19:13:37

Generated On: 11 Aug 2021 22:12:54

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

03 NOV 2020

US3312587

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

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 19:14:00

Generated On: 11 Aug 2021 22:12:54

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

Visit date (dd MMM yyyy)	06 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	UNBLND_DECIDE
------------	---------------

US3312587

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

Form: Unblinding

Data signed: (b) (4) 07 Apr 2021 19:14:00

Generated On: 11 Aug 2021 22:12:54

Date of updated informed consent (<i>dd MMM yyyy</i>)	06 FEB 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>)	06 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3312587

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 07 Apr 2021 19:14:00

Generated On: 11 Aug 2021 22:12:54

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

US3312587

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 07 Apr 2021 19:14:00

Generated On: 11 Aug 2021 22:12:54

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)	06 FEB 2021
Time of assessment (00:00-23:59)	11:58 (24 HR)
Vital Signs Date and Time (derived)	06 FEB 2021 11:58
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3312587

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 07 Apr 2021 19:14:00

Generated On: 11 Aug 2021 22:12:54

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)	06 FEB 2021
Time of assessment (00:00-23:59)	13:39 (24 HR)
Vital Signs Date and Time (derived)	06 FEB 2021 13:39
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3312587

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

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 19:14:00

Generated On: 11 Aug 2021 22:12:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 FEB 2021

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

US3312587

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

Form: Pregnancy Test

Data signed: (b) (4) 07 Apr 2021 19:14:00

Generated On: 11 Aug 2021 22:12:54

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (dd MMM yyyy)	06 FEB 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3312587

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

Form: Exposure

Data signed: (b) (4) 07 Apr 2021 19:14:00

Generated On: 11 Aug 2021 22:12:54

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) 06 FEB 2021

What was the treatment time? (00:00-23:59) 13:08 (24 HR)

Treatment Date and Time (derived) 06 FEB 2021 13:08

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

US3312587

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 19:14:00

Generated On: 11 Aug 2021 22:12:54

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

Collection date (dd MMM yyyy)	06 FEB 2021
-------------------------------	-------------

Collection time (00:00-23:59)	11:29 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	06 FEB 2021 11:29
------------------------------------	-------------------

US3312587

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 07 Apr 2021 19:14:00

Generated On: 11 Aug 2021 22:12:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	06 FEB 2021
Collection time (00:00 - 23:59)	11:28
Collection Date and Time (derived)	06 FEB 2021 11:28

US3312587

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

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 19:14:00

Generated On: 11 Aug 2021 22:12:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312587

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 19:14:01

Generated On: 11 Aug 2021 22:12:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312587

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 19:14:01

Generated On: 11 Aug 2021 22:12:54

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

US3312587

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 19:14:00

Generated On: 11 Aug 2021 22:12:54

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

Visit date (dd MMM yyyy)	06 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	OLD29
------------	-------

US3312587

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 07 Apr 2021 19:14:00

Generated On: 11 Aug 2021 22:12:54

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)	06 MAR 2021
Time of assessment (00:00-23:59)	11:21 (24 HR)
Vital Signs Date and Time (derived)	06 MAR 2021 11:21
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3312587

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 07 Apr 2021 19:14:00

Generated On: 11 Aug 2021 22:12:54

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)	06 MAR 2021
Time of assessment (00:00-23:59)	12:50 (24 HR)
Vital Signs Date and Time (derived)	06 MAR 2021 12:50
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	58 mmHg
Diastolic Blood Pressure units	MMHG

US3312587

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 19:14:00

Generated On: 11 Aug 2021 22:12:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 MAR 2021

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

US3312587

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 07 Apr 2021 19:14:00

Generated On: 11 Aug 2021 22:12:54

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 06 MAR 2021

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

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

US3312587

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 07 Apr 2021 19:14:00

Generated On: 11 Aug 2021 22:12:54

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) 06 MAR 2021

What was the treatment time? (00:00-23:59) 12:19 (24 HR)

Treatment Date and Time (derived) 06 MAR 2021 12:19

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

US3312587

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 19:14:00

Generated On: 11 Aug 2021 22:12:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312587

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 19:14:00

Generated On: 11 Aug 2021 22:12:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312587

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 19:14:00

Generated On: 11 Aug 2021 22:12:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312587

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 19:14:00

Generated On: 11 Aug 2021 22:12:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3312587

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 19:14:00

Generated On: 11 Aug 2021 22:12:54

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) _____

US3312587

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 19:14:00

Generated On: 11 Aug 2021 22:12:54

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.

US3312587

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 19:14:00

Generated On: 11 Aug 2021 22:12:54

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

06 APR 2021

Collection time (00:00-23:59)

13:34 (24 HR)

Collection date and time (derived)

06 APR 2021 13:34

US3312587

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 16:08:48

Generated On: 11 Aug 2021 22:12:54

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3312587

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 16:08:47

Generated On: 11 Aug 2021 22:12:54

AEID	USA-US300-2020-MRNA-1273-P30 1000004
Adverse event	SYMPTOMATIC COVID 19
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 checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	03 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	20 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

406 of 2566

US3312587

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 16:08:47

Generated On: 11 Aug 2021 22:12:54

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

US3312587

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 16:08:47

Generated On: 11 Aug 2021 22:12:54

SUBJECT CALLED WITH MILD
TO MODERATE SYMPTOMS,
ILLNESS VISIT COMPLETED
SAME DAY. POSITIVE RESULTS
RECEIVED TODAY
12OCT2020-SUBJECT HAS NOT
SEE ADDITIONAL
HEALTHCARE PROVIDERS
OTHER THAN SITE, O2 SATS
UPPER 90'S, AND SYMPTOMS
RESOLVING. TOOK OTC MEDS.

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)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 07 Apr 2021 19:13:37

Generated On: 11 Aug 2021 22:12:54

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

Yes ☒

No ☐

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

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 07 Apr 2021 19:13:37

Generated On: 11 Aug 2021 22:12:54

Name of Medication NAPROXEN SODIUM

Prophylaxis Yes ☐
No ☒

Indication RIGHT CARPAL TUNNEL

Dose per administration 220

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

410 of 2566

EAB) (1725)

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 07 Apr 2021 19:13:37

Generated On: 11 Aug 2021 22:12:54

	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)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 07 Apr 2021 19:13:37

Generated On: 11 Aug 2021 22:12:54

Name of Medication EXCEDRIN
(ACETAMINOPHEN/ASPIRIN/CALCITRIOL)
FFEINE)

Prophylaxis Yes ☐
No ☒

Indication OCCASIONAL MIGRAINE

Dose per administration 250/250/65

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)

412 of 2566

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 07 Apr 2021 19:13:37

Generated On: 11 Aug 2021 22:12:54

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2003	
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)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 07 Apr 2021 19:13:37

Generated On: 11 Aug 2021 22:12:54

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

414 of 2566

EAB) (1725)

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 07 Apr 2021 19:13:37

Generated On: 11 Aug 2021 22:12:54

	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 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 07 Apr 2021 19:13:37

Generated On: 11 Aug 2021 22:12:54

Name of Medication SUMATRIPTAN

Prophylaxis Yes ☐
No ☒

Indication OCCASIONAL MIGRAINE

Dose per administration 100

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

416 of 2566

EAB) (1725)

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 07 Apr 2021 19:13:37

Generated On: 11 Aug 2021 22:12:54

	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 2003	
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)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 07 Apr 2021 19:13:37

Generated On: 11 Aug 2021 22:12:54

Name of Medication ADDERALL

Prophylaxis Yes ☐
No ☒

Indication ATTENTION DEFICIT
HYPERACTIVITY DISORDER

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)

418 of 2566

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 07 Apr 2021 19:13:37

Generated On: 11 Aug 2021 22:12:54

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2014
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"/>

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 07 Apr 2021 19:13:37

Generated On: 11 Aug 2021 22:12:54

Name of Medication JUNEL FE (NORETHINDRONE
ACETATE 1MG, ETHINYL
ESTRADIOL 20MCG)

Prophylaxis Yes ☒
No ☐

Indication BIRTH CONTROL

Dose per administration 1

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)

420 of 2566

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 07 Apr 2021 19:13:37

Generated On: 11 Aug 2021 22:12:54

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	21 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 07 Apr 2021 19:13:37

Generated On: 11 Aug 2021 22:12:54

Name of Medication ACETAMINOPHEN
250MG/ASPIRIN 250MG/
CAFFEINE 65MG

Prophylaxis Yes ☐
No ☒

Indication SYMPTOMATIC COVID-19

Dose per administration 2

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)

422 of 2566

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 07 Apr 2021 19:13:37

Generated On: 11 Aug 2021 22:12:54

	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)	05 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 07 Apr 2021 19:13:37

Generated On: 11 Aug 2021 22:12:54

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication SYMPTOMATIC COVID 19

Dose per administration 200

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

424 of 2566

EAB) (1725)

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 07 Apr 2021 19:13:37

Generated On: 11 Aug 2021 22:12:54

	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)		08 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 07 Apr 2021 19:13:37

Generated On: 11 Aug 2021 22:12:54

Name of Medication PHENYLEPHRINE
HYDROCHLORIDE

Prophylaxis Yes ☐
No ☒

Indication SYMPTOMATIC COVID 19

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)

426 of 2566

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 07 Apr 2021 19:13:37

Generated On: 11 Aug 2021 22:12:54

	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)		08 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 07 Apr 2021 19:13:37

Generated On: 11 Aug 2021 22:12:54

Name of Medication TRIAMCINOLONE ACETONIDE

Prophylaxis Yes ☐
No ☒

Indication SYMPTOMATIC COVID 19

Dose per administration 55

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)

428 of 2566

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 07 Apr 2021 19:13:37

Generated On: 11 Aug 2021 22:12:54

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" 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)		11 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 07 Apr 2021 19:13:37

Generated On: 11 Aug 2021 22:12:54

Name of Medication SEASONAL INFLUENZA
VACCINATION

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

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)

430 of 2566

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 07 Apr 2021 19:13:37

Generated On: 11 Aug 2021 22:12:54

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

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 07 Apr 2021 19:13:37

Generated On: 11 Aug 2021 22:12:54

Name of Medication NUVA RING

Prophylaxis Yes ☒
No ☐

Indication BIRTH CONTROL

Dose per administration 1

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

If dose unit is Other, specify UNIT

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)

432 of 2566

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 07 Apr 2021 19:13:37

Generated On: 11 Aug 2021 22:12:54

	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 checked="" type="checkbox"/>
If route of administration is Other, specify	INTRAVAGINAL	
Start date (dd MMM yyyy)	21 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input checked="" type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3312587

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 07 Apr 2021 19:13:37

Generated On: 11 Aug 2021 22:12:54

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3312587

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 07 Apr 2021 19:13:37

Generated On: 11 Aug 2021 22:12:54

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
23 OCT 2020	TUBERCULOSIS SKIN TEST	Diagnostic	

US3312587

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 07 Apr 2021 19:13:59

Generated On: 11 Aug 2021 22:12:54

Date of dosing discontinuation (dd MMM yyyy) 12 OCT 2020

Primary reason for dosing discontinuation

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

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

US3312587

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:12:54

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 ☐

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 07 Apr 2021 19:14:00

Generated On: 11 Aug 2021 22:12:54

SAEID	USA-US300-2020-MRNA-1273-P301000004
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 07 Apr 2021 19:14:00

Generated On: 11 Aug 2021 22:12:54

SAEID	USA-US300-2020-MRNA-1273-P301000004
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	13/OCT/2020 15:32
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 07 Apr 2021 19:14:00

Generated On: 11 Aug 2021 22:12:54

SAEID	USA-US300-2020-MRNA-1273-P301000004
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	22/OCT/2020 21:33
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 07 Apr 2021 19:14:00

Generated On: 11 Aug 2021 22:12:54

SAEID	USA-US300-2020-MRNA-1273-P301000004
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	11/NOV/2020 21:23
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 07 Apr 2021 19:14:00

Generated On: 11 Aug 2021 22:12:54

SAEID	USA-US300-2020-MRNA-1273-P301000004
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	19/NOV/2020 19:43
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3312587 (Prod: Johnson County Clin-Trials)

US3312587

Form: Participant Creation

Generated On: 11 Aug 2021 22:12:54

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'US3312587'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	09 Sep 2020 20:49:25

US3312587

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User closed query 'Per CDM: According to CCGs page 15-16, information is required for Medical History, Vital Signs, Physical Examination, Childbearing potential and Risk of Exposure eCRF forms. Please update as needed. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Oct 2020 20:52:56
Query 'Per CDM: According to CCGs page 15-16, information is required for Medical History, Vital Signs, Physical Examination, Childbearing potential and Risk of Exposure eCRF forms. Please update as needed.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:09:26
' answered with 'UPDATED' (Site from DM).		
User opened query 'Per CDM: According to CCGs page 15-16, information is required for Medical History, Vital Signs, Physical Examination, Childbearing potential and Risk of Exposure eCRF forms. Please update as needed. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 17:33:03
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	09 Sep 2020 21:57:43

US3312587

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '09 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	09 Sep 2020 20:49:27

US3312587

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

[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 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4)	09 Sep 2020 21:57:43

US3312587

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered 'SCRN'	System	09 Sep 2020 21:57:43

US3312587

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:54

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered (b) (6) 1993'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	09 Sep 2020 20:49:28

US3312587

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:54

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '27'	(b) (4) Christa Estrada (b) (4)	09 Sep 2020 21:57:58

US3312587

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:54

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered 'YEARS'	System	09 Sep 2020 21:57:58

US3312587

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:54

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered '27'	System	09 Sep 2020 21:58:15

US3312587

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:54

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Female (F)'	(b) (4) Christa Estrada (b) (4)	09 Sep 2020 21:57:58

US3312587

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:54

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Christa Estrada (b) (4)	09 Sep 2020 21:57:58

US3312587

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:54

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'I'	Christa Estrada (b) (4)	09 Sep 2020 21:57:58

US3312587

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:54

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '0'	Christa Estrada (b) (4)	09 Sep 2020 21:57:58

US3312587

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:54

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '0'	Christa Estrada (b) (4)	09 Sep 2020 21:57:58

US3312587

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:54

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '0'	Christa Estrada (b) (4)	09 Sep 2020 21:57:58

US3312587

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:54

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '0'	Christa Estrada (b) (4)	09 Sep 2020 21:57:58

US3312587

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:54

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '0'	Christa Estrada (b) (4)	09 Sep 2020 21:57:58

US3312587

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:54

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) Christa Estrada (b) (4)	09 Sep 2020 21:57:58

US3312587

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:54

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '0'	Christa Estrada (b) (4)	09 Sep 2020 21:57:58

US3312587

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:54

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '0'	Christa Estrada (b) (4)	09 Sep 2020 21:57:58

US3312587

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:12:54

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '09 Sep 2020' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 17:13:29
User entered '9 Sep 2020'	Karol Moore (b) (4)	09 Sep 2020 21:58:15
	(b) (4)	

US3312587

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered 'Sep 2020'	System	09 Sep 2020 21:58:15

US3312587

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered '2020'	System	09 Sep 2020 21:58:15

US3312587

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:12:54

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Amendment 3 (3)'	Christa Estrada (b) (4)	09 Sep 2020 21:58:15

US3312587

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Yes (Y)'	Christa Estrada (b) (4)	09 Sep 2020 21:58:15

US3312587

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	Christa Estrada (b) (4)	09 Sep 2020 21:58:15

US3312587

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:12:54

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) Christa Estrada (b) (4)	09 Sep 2020 21:58:15

US3312587

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:12:54

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	09 Sep 2020 21:58:15

US3312587

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:12:54

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	09 Sep 2020 20:49:27

US3312587

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:12:54

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered 'I'	System	09 Sep 2020 21:58:19

US3312587

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Yes (Y)'	Christa Estrada (b) (4)	09 Sep 2020 21:58:19

US3312587

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:12:54

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:30:51

US3312587

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:12:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 17:32:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 17:32:42
Data point term sent to Coder	System	29 Sep 2020 17:31:16
User entered 'OCCASIONAL MIGRAINE'	Karol Moore (b) (4)	29 Sep 2020 17:31:07

US3312587

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'UN UNK 2003'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:31:07

US3312587

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:12:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:31:07

US3312587

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:12:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:31:07

US3312587

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:31:07

US3312587

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:12:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:31:07

US3312587

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered 'Jan 2003'	System	29 Sep 2020 17:31:07

US3312587

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered '2003'	System	29 Sep 2020 17:31:07

US3312587

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered empty.	System	29 Sep 2020 17:31:07

US3312587

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered empty.	System	29 Sep 2020 17:31:07

US3312587

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:12:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Carpal tunnel syndrome, LLT: Unilateral carpal tunnel syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 17:33:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 17:33:45
Data point term sent to Coder	System	29 Sep 2020 17:32:16
User entered 'RIGHT CARPAL TUNNEL'	Karol Moore (b) (4)	29 Sep 2020 17:31:17

US3312587

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'UN UNK 2010'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:31:17

US3312587

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:12:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:31:17

US3312587

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:12:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:31:17

US3312587

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:31:17

US3312587

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:12:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:31:17

US3312587

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered 'Jan 2010'	System	29 Sep 2020 17:31:17

US3312587

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered '2010'	System	29 Sep 2020 17:31:17

US3312587

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered empty.	System	29 Sep 2020 17:31:17

US3312587

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered empty.	System	29 Sep 2020 17:31:17

US3312587

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:12:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 17:33:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 17:33:45
Data point term sent to Coder	System	29 Sep 2020 17:32:16
User entered 'ANXIETY'	Karol Moore (b) (4)	29 Sep 2020 17:31:26

US3312587

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'UN UNK 2014'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:31:26

US3312587

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:12:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:31:26

US3312587

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:12:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:31:26

US3312587

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:31:26

US3312587

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:12:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:31:26

US3312587

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered 'Jan 2014'	System	29 Sep 2020 17:31:26

US3312587

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered '2014'	System	29 Sep 2020 17:31:26

US3312587

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered empty.	System	29 Sep 2020 17:31:26

US3312587

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered empty.	System	29 Sep 2020 17:31:26

US3312587

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:12:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 17:33:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 17:33:45
Data point term sent to Coder	System	29 Sep 2020 17:32:17
User entered 'DEPRESSION'	Karol Moore (b) (4)	29 Sep 2020 17:31:34

US3312587

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'UN UNK 2014'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:31:34

US3312587

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:12:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:31:34

US3312587

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:12:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:31:34

US3312587

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:31:34

US3312587

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:12:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:31:34

US3312587

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered 'Jan 2014'	System	29 Sep 2020 17:31:34

US3312587

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered '2014'	System	29 Sep 2020 17:31:34

US3312587

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered empty.	System	29 Sep 2020 17:31:34

US3312587

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered empty.	System	29 Sep 2020 17:31:34

US3312587

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:12:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Fallopian tube therapeutic procedures, PT: Salpingectomy, LLT: Salpingectomy - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 07:47:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 07:47:42
Data point term sent to Coder	System	29 Sep 2020 17:32:17
User entered 'UNILATERAL SALPINGECTOMY'	Karol Moore (b) (4)	29 Sep 2020 17:31:53

US3312587

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'UN UNK 2014'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:31:53

US3312587

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:12:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:31:53

US3312587

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:12:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:31:53

US3312587

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'UN UNK 2014'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:31:53

US3312587

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:12:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:31:53

US3312587

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered 'Jan 2014'	System	29 Sep 2020 17:31:53

US3312587

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered '2014'	System	29 Sep 2020 17:31:53

US3312587

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered 'Jan 2014'	System	29 Sep 2020 17:31:53

US3312587

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered '2014'	System	29 Sep 2020 17:31:53

US3312587

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:12:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Fallopian tube cyst, LLT: Fallopian tube cyst - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 19:14:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 19:14:51
Data point term sent to Coder	System	29 Sep 2020 17:32:18
User entered 'CYST ON FALLOPIAN TUBE'	Karol Moore (b) (4)	29 Sep 2020 17:32:12

US3312587

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'UN UNK 2014'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:32:12

US3312587

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:12:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:32:12

US3312587

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:12:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:32:12

US3312587

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'UN UNK 2014'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:32:12

US3312587

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:12:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:32:12

US3312587

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered 'Jan 2014'	System	29 Sep 2020 17:32:12

US3312587

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered '2014'	System	29 Sep 2020 17:32:12

US3312587

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered 'Jan 2014'	System	29 Sep 2020 17:32:12

US3312587

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered '2014'	System	29 Sep 2020 17:32:12

US3312587

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:12:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 17:33:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 17:33:46
Data point term sent to Coder	System	29 Sep 2020 17:33:18
User entered 'HYPOTHYROIDISM'	Karol Moore (b) (4)	29 Sep 2020 17:32:22

US3312587

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'UN UNK 2016'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:32:22

US3312587

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:12:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:32:22

US3312587

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:12:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:32:22

US3312587

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:32:22

US3312587

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:12:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:32:22

US3312587

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered 'Jan 2016'	System	29 Sep 2020 17:32:22

US3312587

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered '2016'	System	29 Sep 2020 17:32:22

US3312587

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered empty.	System	29 Sep 2020 17:32:22

US3312587

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered empty.	System	29 Sep 2020 17:32:22

US3312587

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:12:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User coded data point as SOC: Psychiatric disorders, HLGT: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: Attention deficit/hyperactivity disorder - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 17:33:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 17:33:47
Data point term sent to Coder	System	29 Sep 2020 17:33:19
User entered 'Attention deficit hyperactivity disorder'	Karol Moore (b) (4)	29 Sep 2020 17:32:34

US3312587

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'UN UNK 2014'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:32:34

US3312587

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:12:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:32:34

US3312587

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:12:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:32:34

US3312587

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:32:34

US3312587

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:12:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:32:34

US3312587

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered 'Jan 2014'	System	29 Sep 2020 17:32:34

US3312587

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered '2014'	System	29 Sep 2020 17:32:34

US3312587

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered empty.	System	29 Sep 2020 17:32:34

US3312587

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered empty.	System	29 Sep 2020 17:32:34

US3312587

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:32:58

US3312587

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '09 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:32:58

US3312587

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '15:53'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:32:58

US3312587

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered '09 Sep 2020 15:53'	System	29 Sep 2020 17:32:58

US3312587

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '67' in	(b) (4)	29 Sep 2020 17:32:58
DataPoint set to visible.	Karol Moore (b) (4)	09 Sep 2020 21:58:19
	(b) (4)	
	System	

US3312587

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '166' lb	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:32:58
DataPoint set to visible.	(b) (4) System	09 Sep 2020 21:58:19

US3312587

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered '26.05364'	System	29 Sep 2020 17:32:58
DataPoint set to visible.	System	09 Sep 2020 21:58:19

US3312587

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered 'kg/m2'	System	29 Sep 2020 17:32:58
DataPoint set to visible.	System	09 Sep 2020 21:58:19

US3312587

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:32:58

US3312587

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:32:58

US3312587

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:32:58

US3312587

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:32:58

US3312587

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered 'bpm'	System	29 Sep 2020 17:32:58

US3312587

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:32:58

US3312587

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered 'breaths/min'	System	29 Sep 2020 17:32:58

US3312587

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:32:58

US3312587

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered 'mmHg'	System	29 Sep 2020 17:32:58

US3312587

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:32:58

US3312587

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered 'mmHg'	System	29 Sep 2020 17:32:58

US3312587

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01

US3312587

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01

US3312587

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:33:07

US3312587

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:54

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '09 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:33:07

US3312587

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:12:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '09 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:33:18

US3312587

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:33:18

US3312587

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:33:18

US3312587

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:12:54

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:33:18

US3312587

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:33:18

US3312587

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:12:54

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:33:18

US3312587

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:33:18

US3312587

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:12:54

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:33:18

US3312587

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:34:16

US3312587

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '09 Sep 2020'	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:34:16

US3312587

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Urine (URINE)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:34:16

US3312587

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Negative (NEGATIVE)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:34:16

US3312587

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:34:16

US3312587

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:34:16

US3312587

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:34:16

US3312587

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User entered empty.	System	29 Sep 2020 17:34:16

US3312587

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:54

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 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:34:02

US3312587

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:54

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 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:34:02

US3312587

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:54

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 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:34:02

US3312587

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:54

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 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:34:02

US3312587

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:54

[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 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:34:02

US3312587

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:54

[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 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:34:02

US3312587

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:54

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 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:34:02

US3312587

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:54

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 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:34:02

US3312587

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:54

[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 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:34:02

US3312587

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:54

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 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:34:02

US3312587

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:54

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 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:34:02

US3312587

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:54

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:34:02

US3312587

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:54

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:34:02

US3312587

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:54

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:34:02

US3312587

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:34:02

US3312587

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:54

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 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:34:02

US3312587

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:54

[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 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '0'	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:34:02

US3312587

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:54

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 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:34:02

US3312587

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '0'	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:34:02

US3312587

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:54

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:34:02

US3312587

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:54

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:23:01
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'RESIDES IN COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:34:02

US3312587

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	09 Sep 2020 21:58:30

US3312587

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '09 Sep 2020' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 17:12:48
User entered '9 Sep 2020'	Karol Moore (b) (4)	09 Sep 2020 21:58:30
	(b) (4)	

US3312587

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

[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 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4)	09 Sep 2020 21:58:30

US3312587

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User entered 'VISIT1'	System	09 Sep 2020 21:58:30

US3312587

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '09 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	09 Sep 2020 21:39:15

US3312587

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '112905'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	09 Sep 2020 21:39:15

US3312587

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	09 Sep 2020 21:39:15

US3312587

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:12:54

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 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'No (N)'	Christa Estrada (b) (4)	09 Sep 2020 21:58:44

US3312587

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:12:54

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 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'No (N)'	Christa Estrada (b) (4)	09 Sep 2020 21:58:44

US3312587

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	09 Sep 2020 21:58:44

US3312587

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	09 Sep 2020 21:58:44

US3312587

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:12:54

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	09 Sep 2020 21:58:44

US3312587

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:34:24
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 05:53:48
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:53:47

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:12:54

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:04

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:12:54

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:04

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:12:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:35:04

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:12:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:04

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4)	29 Sep 2020 17:35:04
	(b) (4)	

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:04

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '09 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:04

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '15:53'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:04

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User entered '09 Sep 2020 15:53'	System	29 Sep 2020 17:35:04

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '98.2' F	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:35:04

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:04

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:04

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '63'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:04

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User entered 'bpm'	System	29 Sep 2020 17:35:04

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '14'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:04

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User entered 'breaths/min'	System	29 Sep 2020 17:35:04

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '125'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:04

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User entered 'mmHg'	System	29 Sep 2020 17:35:04

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '76'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:04

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User entered 'mmHg'	System	29 Sep 2020 17:35:04

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:12:54

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:35:04

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:12:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:04

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:04

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:04

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '09 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:04

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '17:26'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:04

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User entered '09 Sep 2020 17:26'	System	29 Sep 2020 17:35:04

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '98.2' F	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:04

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:04

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:04

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '61'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:04

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User entered 'bpm'	System	29 Sep 2020 17:35:04

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '16'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:04

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User entered 'breaths/min'	System	29 Sep 2020 17:35:04

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '116'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:04

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User entered 'mmHg'	System	29 Sep 2020 17:35:04

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '69'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:04

US3312587

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User entered 'mmHg'	System	29 Sep 2020 17:35:04

US3312587

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:08

US3312587

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:54

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:08

US3312587

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:12

US3312587

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:12

US3312587

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:12

US3312587

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:12

US3312587

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:12

US3312587

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:12

US3312587

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:12

US3312587

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User entered empty.	System	29 Sep 2020 17:35:12

US3312587

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Yes (Y)'	Christa Estrada (b) (4)	09 Sep 2020 21:59:04

US3312587

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	Christa Estrada (b) (4)	09 Sep 2020 21:59:04

US3312587

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

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 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	Christa Estrada (b) (4)	09 Sep 2020 21:59:04

US3312587

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User entered 'MRNA-1273 OR PLACEBO'	System	09 Sep 2020 21:59:04

US3312587

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User closed query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020).	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:54:32
' (Site from DM).		
Query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020).	Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:44:48
' answered with 'updated' (Site from DM).		
User entered '09 Sep 2020' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:44:42
User opened query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020).	(b) (4), (b) (6)	14 Oct 2020 15:47:37
' (Site from DM).		
User entered '9 Sep 2020'	Christa Estrada (b) (4) (b) (4)	09 Sep 2020 21:59:04

US3312587

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '16:55'	Christa Estrada (b) (4)	09 Sep 2020 21:59:04

US3312587

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User entered '09 Sep 2020 16:55'	System	21 Oct 2020 16:44:42
User entered '9 Sep 2020 16:55'	System	09 Sep 2020 21:59:04

US3312587

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Left Arm (LEFT ARM)'	Christa Estrada (b) (4)	09 Sep 2020 21:59:04

US3312587

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User entered 'ONCE'	System	09 Sep 2020 21:59:04

US3312587

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User entered 'INTRAMUSCULAR'	System	09 Sep 2020 21:59:04

US3312587

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:26

US3312587

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '09 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:26

US3312587

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '16:25'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:26

US3312587

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User entered '09 Sep 2020 16:25'	System	29 Sep 2020 17:35:26

US3312587

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:12:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '09 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:35

US3312587

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:12:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:35

US3312587

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:12:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:35

US3312587

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '16:21'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:35

US3312587

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User entered '09 Sep 2020 16:21'	System	29 Sep 2020 17:35:35

US3312587

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:12:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:35

US3312587

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:12:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:35

US3312587

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:12:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:35

US3312587

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User entered empty.	System	29 Sep 2020 17:35:35

US3312587

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:38

US3312587

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:12:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User entered 'I'	System	29 Sep 2020 17:35:38

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
Data entry locked.	System	09 Sep 2020 21:59:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:12:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-09T17:25:11', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '2350d989-52d9-4c09-8c27-786b2aff3c95'	System	09 Sep 2020 22:25:40
User entered 'Yes (Y)'	System	09 Sep 2020 22:25:40

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:12:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-09T17:25:15', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '2350d989-52d9-4c09-8c27-786b2aff3c95' User entered '98.2'	System	09 Sep 2020 22:25:40
	System	09 Sep 2020 22:25:40

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-09T17:25:27', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '2350d989-52d9-4c09-8c27-786b2aff3c95'	System	09 Sep 2020 22:25:40
User entered 'No (N)'	System	09 Sep 2020 22:25:40

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:12:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-09T17:25:36', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '2350d989-52d9-4c09-8c27-786b2aff3c95'	System	09 Sep 2020 22:25:40
User entered '09 Sep 2020 17:25'	System	09 Sep 2020 22:25:40

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:12:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '09 Sep 2020 17:15'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:12:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '09 Sep 2020 19:45'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
Data entry locked.	System	09 Sep 2020 21:59:04
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:12:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-09T21:42:31', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '25f7b10f-d75a-4c2d-bcae-9bea80645789' User entered 'Yes (Y)'	System	10 Sep 2020 02:42:45
	System	10 Sep 2020 02:42:45

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:12:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-09T21:42:35', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '25f7b10f-d75a-4c2d-bcae-9bea80645789' User entered '98.6'	System	10 Sep 2020 02:42:45
	System	10 Sep 2020 02:42:45

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-09T21:42:38', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '25f7b10f-d75a-4c2d-bcae-9bea80645789' User entered 'No (N)'	System	10 Sep 2020 02:42:45
	System	10 Sep 2020 02:42:45

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:12:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-09T21:42:43', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '25f7b10f-d75a-4c2d-bcae-9bea80645789' User entered '09 Sep 2020 21:42'	System	10 Sep 2020 02:42:45
	System	10 Sep 2020 02:42:45

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:12:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '09 Sep 2020 20:40'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:12:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
Data entry locked.	System	09 Sep 2020 21:59:04
User entered 'Day 2'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:12:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-10T23:23:22', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'f2195b57-fa45-474a-893a-e8d137a9fa94'	System	11 Sep 2020 04:23:36
User entered 'Yes (Y)'	System	11 Sep 2020 04:23:36

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:12:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-10T23:23:26', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'f2195b57-fa45-474a-893a-e8d137a9fa94' User entered '97.3'	System	11 Sep 2020 04:23:36
	System	11 Sep 2020 04:23:36

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-10T23:23:29', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'f2195b57-fa45-474a-893a-e8d137a9fa94'	System	11 Sep 2020 04:23:36
User entered 'No (N)'	System	11 Sep 2020 04:23:36

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:12:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-10T23:23:33', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'f2195b57-fa45-474a-893a-e8d137a9fa94' User entered '10 Sep 2020 23:23'	System	11 Sep 2020 04:23:36
	System	11 Sep 2020 04:23:36

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:12:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:12:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
Data entry locked.	System	09 Sep 2020 21:59:04
User entered 'Day 3'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:12:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-11T20:44:09', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'caa2db5e-1107-4b55-b748-110b01f30e6e' User entered 'Yes (Y)'	System	12 Sep 2020 01:44:27
	System	12 Sep 2020 01:44:27

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:12:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-11T20:44:13', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'caa2db5e-1107-4b55-b748-110b01f30e6e' User entered '97.4'	System	12 Sep 2020 01:44:27
	System	12 Sep 2020 01:44:27

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-11T20:44:16', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'caa2db5e-1107-4b55-b748-110b01f30e6e' User entered 'No (N)'	System	12 Sep 2020 01:44:27
	System	12 Sep 2020 01:44:27

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:12:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-11T20:44:22', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'caa2db5e-1107-4b55-b748-110b01f30e6e' User entered '11 Sep 2020 20:44'	System	12 Sep 2020 01:44:27
	System	12 Sep 2020 01:44:27

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:12:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:12:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
Data entry locked.	System	09 Sep 2020 21:59:04
User entered 'Day 4'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:12:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-12T20:57:43', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'de9f7d1d-e636-4717-a0e6-a423727de17c' User entered 'Yes (Y)'	System	13 Sep 2020 01:58:11
	System	13 Sep 2020 01:58:11

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:12:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-12T20:57:47', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'de9f7d1d-e636-4717-a0e6-a423727de17c' User entered '96.4'	System	13 Sep 2020 01:58:11
	System	13 Sep 2020 01:58:11

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-12T20:57:50', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'de9f7d1d-e636-4717-a0e6-a423727de17c' User entered 'No (N)'	System	13 Sep 2020 01:58:11
	System	13 Sep 2020 01:58:11

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:12:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-12T20:57:54', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'de9f7d1d-e636-4717-a0e6-a423727de17c' User entered '12 Sep 2020 20:57'	System	13 Sep 2020 01:58:11
	System	13 Sep 2020 01:58:11

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:12:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:12:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
Data entry locked.	System	09 Sep 2020 21:59:04
User entered 'Day 5'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:12:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-14T10:00:04', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '46a28868-6339-4f5a-b539-a4b707d06f63' User entered 'Yes (Y)'	System	14 Sep 2020 15:01:12
	System	14 Sep 2020 15:01:12

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:12:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-14T10:00:32', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '46a28868-6339-4f5a-b539-a4b707d06f63' User entered '97.6'	System	14 Sep 2020 15:01:12
	System	14 Sep 2020 15:01:12

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-14T10:01:06', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '46a28868-6339-4f5a-b539-a4b707d06f63'	System	14 Sep 2020 15:01:12
User entered 'No (N)'	System	14 Sep 2020 15:01:12

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:12:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-14T10:01:09', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '46a28868-6339-4f5a-b539-a4b707d06f63' User entered '14 Sep 2020 10:01'	System	14 Sep 2020 15:01:12
	System	14 Sep 2020 15:01:12

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:12:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:12:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
Data entry locked.	System	09 Sep 2020 21:59:04
User entered 'Day 6'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:12:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-14T22:51:26', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '5a70c5cc-9098-485e-a8c9-7d1cded069d2'	System	15 Sep 2020 03:51:43
User entered 'Yes (Y)'	System	15 Sep 2020 03:51:43

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:12:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-14T22:51:30', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '5a70c5cc-9098-485e-a8c9-7d1cded069d2' User entered '97.6'	System	15 Sep 2020 03:51:43
	System	15 Sep 2020 03:51:43

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-14T22:51:33', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '5a70c5cc-9098-485e-a8c9-7d1cded069d2'	System	15 Sep 2020 03:51:43
User entered 'No (N)'	System	15 Sep 2020 03:51:43

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:12:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-14T22:51:37', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '5a70c5cc-9098-485e-a8c9-7d1cded069d2' User entered '14 Sep 2020 22:51'	System	15 Sep 2020 03:51:43
	System	15 Sep 2020 03:51:43

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:12:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:12:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
Data entry locked.	System	09 Sep 2020 21:59:04
User entered 'Day 7'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:12:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-15T21:43:56', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '95a3d510-97b0-4403-b744-d4b8d9b09583' User entered 'Yes (Y)'	System	16 Sep 2020 02:44:08
	System	16 Sep 2020 02:44:08

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:12:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-15T21:43:59', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '95a3d510-97b0-4403-b744-d4b8d9b09583' User entered '98.1'	System	16 Sep 2020 02:44:08
	System	16 Sep 2020 02:44:08

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-15T21:44:02', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '95a3d510-97b0-4403-b744-d4b8d9b09583' User entered 'No (N)'	System	16 Sep 2020 02:44:08
	System	16 Sep 2020 02:44:08

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:12:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-15T21:44:04', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '95a3d510-97b0-4403-b744-d4b8d9b09583' User entered '15 Sep 2020 21:44'	System	16 Sep 2020 02:44:08
	System	16 Sep 2020 02:44:08

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:12:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:12:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
Data entry locked.	System	09 Sep 2020 21:59:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:12:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-09T17:25:41', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'faba40ad-b364-498c-8e92-2ab3e97c80c3'	System	09 Sep 2020 22:25:56
User entered 'None (1)'	System	09 Sep 2020 22:25:56

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:12:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-09T17:25:44', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'faba40ad-b364-498c-8e92-2ab3e97c80c3' User entered 'No (N)'	System	09 Sep 2020 22:25:56
	System	09 Sep 2020 22:25:56

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-09T17:25:47', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'faba40ad-b364-498c-8e92-2ab3e97c80c3' User entered 'No (N)'	System	09 Sep 2020 22:25:56
	System	09 Sep 2020 22:25:56

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:12:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-09T17:25:51', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'faba40ad-b364-498c-8e92-2ab3e97c80c3' User entered 'None (1)'	System	09 Sep 2020 22:25:56
	System	09 Sep 2020 22:25:56

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:12:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-09T17:25:53', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'faba40ad-b364-498c-8e92-2ab3e97c80c3' User entered '09 Sep 2020 17:25'	System	09 Sep 2020 22:25:56
	System	09 Sep 2020 22:25:56

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:12:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '09 Sep 2020 17:15'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:12:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '09 Sep 2020 19:45'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
Data entry locked.	System	09 Sep 2020 21:59:04
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:12:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-09T21:13:25', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '39c12324-ae76-4c48-94f9-2e39b1a37a63' User entered 'None (1)'	System	10 Sep 2020 02:14:22
	System	10 Sep 2020 02:14:22

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:12:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-09T21:13:29', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '39c12324-ae76-4c48-94f9-2e39b1a37a63' User entered 'No (N)'	System	10 Sep 2020 02:14:22
	System	10 Sep 2020 02:14:22

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-09T21:13:38', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '39c12324-ae76-4c48-94f9-2e39b1a37a63' User entered 'No (N)'	System	10 Sep 2020 02:14:22
	System	10 Sep 2020 02:14:22

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:12:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-09T21:14:13', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '39c12324-ae76-4c48-94f9-2e39b1a37a63' User entered 'None (1)'	System	10 Sep 2020 02:14:22
	System	10 Sep 2020 02:14:22

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:12:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-09T21:14:17', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '39c12324-ae76-4c48-94f9-2e39b1a37a63' User entered '09 Sep 2020 21:14'	System	10 Sep 2020 02:14:22
	System	10 Sep 2020 02:14:22

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:12:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '09 Sep 2020 20:40'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:12:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
Data entry locked.	System	09 Sep 2020 21:59:04
User entered 'Day 2'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:12:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-10T23:19:19', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '6f34db4c-529b-4962-9630-27fe522e46ca' User entered 'None (1)'	System	11 Sep 2020 04:20:07
	System	11 Sep 2020 04:20:07

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:12:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-10T23:19:21', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '6f34db4c-529b-4962-9630-27fe522e46ca' User entered 'No (N)'	System	11 Sep 2020 04:20:07
	System	11 Sep 2020 04:20:07

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-10T23:19:27', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '6f34db4c-529b-4962-9630-27fe522e46ca' User entered 'No (N)'	System	11 Sep 2020 04:20:07
	System	11 Sep 2020 04:20:07

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:12:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-10T23:19:49', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '6f34db4c-529b-4962-9630-27fe522e46ca' User entered 'None (1)'	System	11 Sep 2020 04:20:07
	System	11 Sep 2020 04:20:07

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:12:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-10T23:20:04', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '6f34db4c-529b-4962-9630-27fe522e46ca' User entered '10 Sep 2020 23:20'	System	11 Sep 2020 04:20:07
	System	11 Sep 2020 04:20:07

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:12:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:12:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
Data entry locked.	System	09 Sep 2020 21:59:04
User entered 'Day 3'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:12:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-11T20:44:29', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '3c10978f-f608-4b97-bbf3-bd2aa2fefdf1'	System	12 Sep 2020 01:45:09
User entered 'None (1)'	System	12 Sep 2020 01:45:09

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:12:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-11T20:44:34', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '3c10978f-f608-4b97-bbf3-bd2aa2fefdf1' User entered 'No (N)'	System	12 Sep 2020 01:45:09
	System	12 Sep 2020 01:45:09

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-11T20:44:37', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '3c10978f-f608-4b97-bbf3-bd2aa2fefdf1' User entered 'No (N)'	System	12 Sep 2020 01:45:09
	System	12 Sep 2020 01:45:09

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:12:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-11T20:45:01', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '3c10978f-f608-4b97-bbf3-bd2aa2fefdf1'	System	12 Sep 2020 01:45:09
User entered 'None (1)'	System	12 Sep 2020 01:45:09

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:12:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-11T20:45:05', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '3c10978f-f608-4b97-bbf3-bd2aa2fefdf1'	System	12 Sep 2020 01:45:09
User entered '11 Sep 2020 20:45'	System	12 Sep 2020 01:45:09

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:12:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:12:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
Data entry locked.	System	09 Sep 2020 21:59:04
User entered 'Day 4'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:12:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-12T20:56:27', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '0185e7d4-c9d1-4d50-8182-59014983db35'	System	13 Sep 2020 01:56:39
User entered 'None (1)'	System	13 Sep 2020 01:56:39

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:12:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-12T20:56:29', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '0185e7d4-c9d1-4d50-8182-59014983db35' User entered 'No (N)'	System	13 Sep 2020 01:56:39
	System	13 Sep 2020 01:56:39

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-12T20:56:31', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '0185e7d4-c9d1-4d50-8182-59014983db35' User entered 'No (N)'	System	13 Sep 2020 01:56:39
	System	13 Sep 2020 01:56:39

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:12:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-12T20:56:34', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '0185e7d4-c9d1-4d50-8182-59014983db35'	System	13 Sep 2020 01:56:39
User entered 'None (1)'	System	13 Sep 2020 01:56:39

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:12:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-12T20:56:37', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '0185e7d4-c9d1-4d50-8182-59014983db35'	System	13 Sep 2020 01:56:39
User entered '12 Sep 2020 20:56'	System	13 Sep 2020 01:56:39

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:12:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:12:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
Data entry locked.	System	09 Sep 2020 21:59:04
User entered 'Day 5'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:12:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-14T09:57:59', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '6135e47a-6358-4300-b7b1-fc4e68243350' User entered 'None (1)'	System	14 Sep 2020 14:58:12
	System	14 Sep 2020 14:58:12

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:12:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-14T09:58:02', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '6135e47a-6358-4300-b7b1-fc4e68243350' User entered 'No (N)'	System	14 Sep 2020 14:58:12
	System	14 Sep 2020 14:58:12

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-14T09:58:05', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '6135e47a-6358-4300-b7b1-fc4e68243350' User entered 'No (N)'	System	14 Sep 2020 14:58:12
	System	14 Sep 2020 14:58:12

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:12:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-14T09:58:08', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '6135e47a-6358-4300-b7b1-fc4e68243350' User entered 'None (1)'	System	14 Sep 2020 14:58:12
	System	14 Sep 2020 14:58:12

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:12:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-14T09:58:10', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '6135e47a-6358-4300-b7b1-fc4e68243350' User entered '14 Sep 2020 09:58'	System	14 Sep 2020 14:58:12
	System	14 Sep 2020 14:58:12

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:12:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:12:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
Data entry locked.	System	09 Sep 2020 21:59:04
User entered 'Day 6'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:12:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-14T22:51:00', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'a3687c83-afab-444f-8023-7dc684d30e08' User entered 'None (1)'	System	15 Sep 2020 03:51:11
	System	15 Sep 2020 03:51:11

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:12:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-14T22:51:02', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'a3687c83-afab-444f-8023-7dc684d30e08' User entered 'No (N)'	System	15 Sep 2020 03:51:11
	System	15 Sep 2020 03:51:11

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-14T22:51:03', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'a3687c83-afab-444f-8023-7dc684d30e08' User entered 'No (N)'	System	15 Sep 2020 03:51:11
	System	15 Sep 2020 03:51:11

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:12:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-14T22:51:05', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'a3687c83-afab-444f-8023-7dc684d30e08' User entered 'None (1)'	System	15 Sep 2020 03:51:11
	System	15 Sep 2020 03:51:11

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:12:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-14T22:51:08', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'a3687c83-afab-444f-8023-7dc684d30e08' User entered '14 Sep 2020 22:51'	System	15 Sep 2020 03:51:11
	System	15 Sep 2020 03:51:11

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:12:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:12:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
Data entry locked.	System	09 Sep 2020 21:59:04
User entered 'Day 7'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:12:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-15T21:44:12', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '186ccea9-ca89-4567-b8c7-2a2443d7070e' User entered 'None (1)'	System	16 Sep 2020 02:44:34
	System	16 Sep 2020 02:44:34

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:12:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-15T21:44:24', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '186ccea9-ca89-4567-b8c7-2a2443d7070e' User entered 'No (N)'	System	16 Sep 2020 02:44:34
	System	16 Sep 2020 02:44:34

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-15T21:44:26', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '186ccea9-ca89-4567-b8c7-2a2443d7070e' User entered 'No (N)'	System	16 Sep 2020 02:44:34
	System	16 Sep 2020 02:44:34

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:12:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-15T21:44:29', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '186ccea9-ca89-4567-b8c7-2a2443d7070e' User entered 'None (1)'	System	16 Sep 2020 02:44:34
	System	16 Sep 2020 02:44:34

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:12:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-15T21:44:31', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '186ccea9-ca89-4567-b8c7-2a2443d7070e' User entered '15 Sep 2020 21:44'	System	16 Sep 2020 02:44:34
	System	16 Sep 2020 02:44:34

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:12:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:12:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
Data entry locked.	System	09 Sep 2020 21:59:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-09T17:25:58', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '000167dc-da83-4a13-a15b-ea6bb98f4d49' User entered 'None (0)'	System	09 Sep 2020 22:26:23
	System	09 Sep 2020 22:26:23

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-09T17:26:01', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '000167dc-da83-4a13-a15b-ea6bb98f4d49' User entered 'None (0)'	System	09 Sep 2020 22:26:23
	System	09 Sep 2020 22:26:23

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-09T17:26:06', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '000167dc-da83-4a13-a15b-ea6bb98f4d49' User entered 'None (0)'	System	09 Sep 2020 22:26:23
	System	09 Sep 2020 22:26:23

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-09T17:26:08', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '000167dc-da83-4a13-a15b-ea6bb98f4d49' User entered 'None (0)'	System	09 Sep 2020 22:26:23
	System	09 Sep 2020 22:26:23

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-09T17:26:10', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '000167dc-da83-4a13-a15b-ea6bb98f4d49' User entered 'None (0)'	System	09 Sep 2020 22:26:23
	System	09 Sep 2020 22:26:23

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-09T17:26:13', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '000167dc-da83-4a13-a15b-ea6bb98f4d49' User entered 'None (0)'	System	09 Sep 2020 22:26:23
	System	09 Sep 2020 22:26:23

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-09T17:26:18', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '000167dc-da83-4a13-a15b-ea6bb98f4d49' User entered 'No (N)'	System	09 Sep 2020 22:26:23
	System	09 Sep 2020 22:26:23

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-09T17:26:20', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '000167dc-da83-4a13-a15b-ea6bb98f4d49' User entered '09 Sep 2020 17:26'	System	09 Sep 2020 22:26:23
	System	09 Sep 2020 22:26:23

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '09 Sep 2020 17:15'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '09 Sep 2020 19:45'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
Data entry locked.	System	09 Sep 2020 21:59:04
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-09T21:14:24', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '5216e0cb-35e9-4224-8af1-bb26a2c263fc' User entered 'None (0)'	System	10 Sep 2020 02:15:10
	System	10 Sep 2020 02:15:10

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-09T21:14:27', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '5216e0cb-35e9-4224-8af1-bb26a2c263fc' User entered 'None (0)'	System	10 Sep 2020 02:15:10
	System	10 Sep 2020 02:15:10

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-09T21:14:33', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '5216e0cb-35e9-4224-8af1-bb26a2c263fc' User entered 'None (0)'	System	10 Sep 2020 02:15:10
	System	10 Sep 2020 02:15:10

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-09T21:14:35', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '5216e0cb-35e9-4224-8af1-bb26a2c263fc' User entered 'None (0)'	System	10 Sep 2020 02:15:10
	System	10 Sep 2020 02:15:10

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-09T21:14:55', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '5216e0cb-35e9-4224-8af1-bb26a2c263fc' User entered 'None (0)'	System	10 Sep 2020 02:15:10
	System	10 Sep 2020 02:15:10

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-09T21:14:57', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '5216e0cb-35e9-4224-8af1-bb26a2c263fc' User entered 'None (0)'	System	10 Sep 2020 02:15:10
	System	10 Sep 2020 02:15:10

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-09T21:15:02', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '5216e0cb-35e9-4224-8af1-bb26a2c263fc' User entered 'No (N)'	System	10 Sep 2020 02:15:10
	System	10 Sep 2020 02:15:10

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-09T21:15:09', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '5216e0cb-35e9-4224-8af1-bb26a2c263fc' User entered '09 Sep 2020 21:15'	System	10 Sep 2020 02:15:10
	System	10 Sep 2020 02:15:10

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '09 Sep 2020 20:40'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
Data entry locked.	System	09 Sep 2020 21:59:04
User entered 'Day 2'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:12:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-10T23:20:08', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '30efae09-55d2-4a72-b505-40e4f83b6573' User entered 'None (0)'	System	11 Sep 2020 04:20:28
	System	11 Sep 2020 04:20:28

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:12:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-10T23:20:09', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '30efae09-55d2-4a72-b505-40e4f83b6573' User entered 'None (0)'	System	11 Sep 2020 04:20:28
	System	11 Sep 2020 04:20:28

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:12:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-10T23:20:11', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '30efae09-55d2-4a72-b505-40e4f83b6573' User entered 'None (0)'	System	11 Sep 2020 04:20:28
	System	11 Sep 2020 04:20:28

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:12:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-10T23:20:13', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '30efae09-55d2-4a72-b505-40e4f83b6573' User entered 'None (0)'	System	11 Sep 2020 04:20:28
	System	11 Sep 2020 04:20:28

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:12:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-10T23:20:15', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '30efae09-55d2-4a72-b505-40e4f83b6573' User entered 'None (0)'	System	11 Sep 2020 04:20:28
	System	11 Sep 2020 04:20:28

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:12:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-10T23:20:17', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '30efae09-55d2-4a72-b505-40e4f83b6573' User entered 'None (0)'	System	11 Sep 2020 04:20:28
	System	11 Sep 2020 04:20:28

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-10T23:20:20', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '30efae09-55d2-4a72-b505-40e4f83b6573' User entered 'No (N)'	System	11 Sep 2020 04:20:28
	System	11 Sep 2020 04:20:28

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:12:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-10T23:20:26', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '30efae09-55d2-4a72-b505-40e4f83b6573' User entered '10 Sep 2020 23:20'	System	11 Sep 2020 04:20:28
	System	11 Sep 2020 04:20:28

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:12:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:12:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
Data entry locked.	System	09 Sep 2020 21:59:04
User entered 'Day 3'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:12:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-11T20:45:09', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '1b26e6c4-bbaf-4aef-be1f-4f0dad46f9c7' User entered 'None (0)'	System	12 Sep 2020 01:45:35
	System	12 Sep 2020 01:45:35

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:12:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-11T20:45:10', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '1b26e6c4-bbaf-4aef-be1f-4f0dad46f9c7' User entered 'None (0)'	System	12 Sep 2020 01:45:35
	System	12 Sep 2020 01:45:35

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:12:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-11T20:45:14', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '1b26e6c4-bbaf-4aef-be1f-4f0dad46f9c7' User entered 'None (0)'	System	12 Sep 2020 01:45:35
	System	12 Sep 2020 01:45:35

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:12:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-11T20:45:17', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '1b26e6c4-bbaf-4aef-be1f-4f0dad46f9c7' User entered 'None (0)'	System	12 Sep 2020 01:45:35
	System	12 Sep 2020 01:45:35

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:12:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-11T20:45:20', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '1b26e6c4-bbaf-4aef-be1f-4f0dad46f9c7' User entered 'None (0)'	System	12 Sep 2020 01:45:35
	System	12 Sep 2020 01:45:35

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:12:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-11T20:45:22', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '1b26e6c4-bbaf-4aef-be1f-4f0dad46f9c7' User entered 'None (0)'	System	12 Sep 2020 01:45:35
	System	12 Sep 2020 01:45:35

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-11T20:45:26', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '1b26e6c4-bbaf-4aef-be1f-4f0dad46f9c7'	System	12 Sep 2020 01:45:35
User entered 'No (N)'	System	12 Sep 2020 01:45:35

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:12:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-11T20:45:32', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '1b26e6c4-bbaf-4aef-be1f-4f0dad46f9c7'	System	12 Sep 2020 01:45:35
User entered '11 Sep 2020 20:45'	System	12 Sep 2020 01:45:35

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:12:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:12:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
Data entry locked.	System	09 Sep 2020 21:59:04
User entered 'Day 4'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:12:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-12T20:56:40', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '6519ec28-6ad5-4ea2-ba43-fe30de3cfa85' User entered 'None (0)'	System	13 Sep 2020 01:56:57
	System	13 Sep 2020 01:56:57

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:12:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-12T20:56:42', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '6519ec28-6ad5-4ea2-ba43-fe30de3cfa85' User entered 'None (0)'	System	13 Sep 2020 01:56:57
	System	13 Sep 2020 01:56:57

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:12:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-12T20:56:44', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '6519ec28-6ad5-4ea2-ba43-fe30de3cfa85' User entered 'None (0)'	System	13 Sep 2020 01:56:57
	System	13 Sep 2020 01:56:57

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:12:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-12T20:56:46', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '6519ec28-6ad5-4ea2-ba43-fe30de3cfa85' User entered 'None (0)'	System	13 Sep 2020 01:56:57
	System	13 Sep 2020 01:56:57

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:12:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-12T20:56:48', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '6519ec28-6ad5-4ea2-ba43-fe30de3cfa85' User entered 'None (0)'	System	13 Sep 2020 01:56:57
	System	13 Sep 2020 01:56:57

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:12:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-12T20:56:49', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '6519ec28-6ad5-4ea2-ba43-fe30de3cfa85' User entered 'None (0)'	System	13 Sep 2020 01:56:57
	System	13 Sep 2020 01:56:57

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-12T20:56:51', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '6519ec28-6ad5-4ea2-ba43-fe30de3cfa85' User entered 'No (N)'	System	13 Sep 2020 01:56:57
	System	13 Sep 2020 01:56:57

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:12:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-12T20:56:54', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '6519ec28-6ad5-4ea2-ba43-fe30de3cfa85' User entered '12 Sep 2020 20:56'	System	13 Sep 2020 01:56:57
	System	13 Sep 2020 01:56:57

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:12:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:12:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
Data entry locked.	System	09 Sep 2020 21:59:04
User entered 'Day 5'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:12:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-14T09:58:13', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'da51336f-69fd-4381-a89f-ac2f73965be8' User entered 'None (0)'	System	14 Sep 2020 14:58:27
	System	14 Sep 2020 14:58:27

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:12:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-14T09:58:15', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'da51336f-69fd-4381-a89f-ac2f73965be8' User entered 'None (0)'	System	14 Sep 2020 14:58:27
	System	14 Sep 2020 14:58:27

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:12:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-14T09:58:16', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'da51336f-69fd-4381-a89f-ac2f73965be8' User entered 'None (0)'	System	14 Sep 2020 14:58:27
	System	14 Sep 2020 14:58:27

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:12:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-14T09:58:18', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'da51336f-69fd-4381-a89f-ac2f73965be8' User entered 'None (0)'	System	14 Sep 2020 14:58:27
	System	14 Sep 2020 14:58:27

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:12:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-14T09:58:19', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'da51336f-69fd-4381-a89f-ac2f73965be8' User entered 'None (0)'	System	14 Sep 2020 14:58:27
	System	14 Sep 2020 14:58:27

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:12:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-14T09:58:21', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'da51336f-69fd-4381-a89f-ac2f73965be8' User entered 'None (0)'	System	14 Sep 2020 14:58:27
	System	14 Sep 2020 14:58:27

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-14T09:58:23', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'da51336f-69fd-4381-a89f-ac2f73965be8' User entered 'No (N)'	System	14 Sep 2020 14:58:27
	System	14 Sep 2020 14:58:27

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:12:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-14T09:58:25', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'da51336f-69fd-4381-a89f-ac2f73965be8' User entered '14 Sep 2020 09:58'	System	14 Sep 2020 14:58:27
	System	14 Sep 2020 14:58:27

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:12:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:12:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
Data entry locked.	System	09 Sep 2020 21:59:04
User entered 'Day 6'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:12:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-14T22:50:45', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'ac0a3f93-7a8c-4b52-90d3-3b447d885aae' User entered 'None (0)'	System	15 Sep 2020 03:50:59
	System	15 Sep 2020 03:50:59

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:12:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-14T22:50:46', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'ac0a3f93-7a8c-4b52-90d3-3b447d885aae' User entered 'None (0)'	System	15 Sep 2020 03:50:59
	System	15 Sep 2020 03:50:59

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:12:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-14T22:50:48', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'ac0a3f93-7a8c-4b52-90d3-3b447d885aae' User entered 'None (0)'	System	15 Sep 2020 03:50:59
	System	15 Sep 2020 03:50:59

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:12:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-14T22:50:49', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'ac0a3f93-7a8c-4b52-90d3-3b447d885aae' User entered 'None (0)'	System	15 Sep 2020 03:50:59
	System	15 Sep 2020 03:50:59

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:12:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-14T22:50:50', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'ac0a3f93-7a8c-4b52-90d3-3b447d885aae' User entered 'None (0)'	System	15 Sep 2020 03:50:59
	System	15 Sep 2020 03:50:59

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:12:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-14T22:50:52', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'ac0a3f93-7a8c-4b52-90d3-3b447d885aae' User entered 'None (0)'	System	15 Sep 2020 03:50:59
	System	15 Sep 2020 03:50:59

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-14T22:50:53', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'ac0a3f93-7a8c-4b52-90d3-3b447d885aae' User entered 'No (N)'	System	15 Sep 2020 03:50:59
	System	15 Sep 2020 03:50:59

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:12:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-14T22:50:56', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'ac0a3f93-7a8c-4b52-90d3-3b447d885aae' User entered '14 Sep 2020 22:50'	System	15 Sep 2020 03:50:59
	System	15 Sep 2020 03:50:59

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:12:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:12:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
Data entry locked.	System	09 Sep 2020 21:59:04
User entered 'Day 7'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:12:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-15T21:44:34', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'e167c82d-501c-4803-97f0-a40977b32d65' User entered 'None (0)'	System	16 Sep 2020 02:44:49
	System	16 Sep 2020 02:44:49

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:12:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-15T21:44:36', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'e167c82d-501c-4803-97f0-a40977b32d65' User entered 'None (0)'	System	16 Sep 2020 02:44:49
	System	16 Sep 2020 02:44:49

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:12:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-15T21:44:37', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'e167c82d-501c-4803-97f0-a40977b32d65' User entered 'None (0)'	System	16 Sep 2020 02:44:49
	System	16 Sep 2020 02:44:49

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:12:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-15T21:44:39', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'e167c82d-501c-4803-97f0-a40977b32d65' User entered 'None (0)'	System	16 Sep 2020 02:44:49
	System	16 Sep 2020 02:44:49

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:12:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-15T21:44:40', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'e167c82d-501c-4803-97f0-a40977b32d65' User entered 'None (0)'	System	16 Sep 2020 02:44:49
	System	16 Sep 2020 02:44:49

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:12:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-15T21:44:41', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'e167c82d-501c-4803-97f0-a40977b32d65' User entered 'None (0)'	System	16 Sep 2020 02:44:49
	System	16 Sep 2020 02:44:49

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-15T21:44:43', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'e167c82d-501c-4803-97f0-a40977b32d65' User entered 'No (N)'	System	16 Sep 2020 02:44:49
	System	16 Sep 2020 02:44:49

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:12:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-09-15T21:44:47', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'e167c82d-501c-4803-97f0-a40977b32d65' User entered '15 Sep 2020 21:44'	System	16 Sep 2020 02:44:49
	System	16 Sep 2020 02:44:49

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:12:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 21:59:04

US3312587

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:12:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 21:59:04

US3312587

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:49

US3312587

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	29 Sep 2020 17:36:10
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	29 Sep 2020 17:36:10
User entered '17 Sep 2020' reason for change: Data Entry Error	Karol Moore (b) (4)	29 Sep 2020 17:36:10
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	29 Sep 2020 17:35:49
User entered '09 Sep 2020'	System	29 Sep 2020 17:35:49
	Karol Moore (b) (4)	29 Sep 2020 17:35:49
	(b) (4)	

US3312587

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:35:49

US3312587

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4)	29 Sep 2020 17:35:49
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:36:13

US3312587

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User entered 'I'	System	29 Sep 2020 17:36:13

US3312587

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:36:23

US3312587

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '23 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:36:23

US3312587

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:36:23

US3312587

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4)	29 Sep 2020 17:36:23
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:36:26

US3312587

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:05:42
User entered 'I'	System	29 Sep 2020 17:36:26

US3312587

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:10:08
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:28:41

US3312587

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:10:08
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered '30 Sep 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:28:41

US3312587

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:10:08
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:28:41

US3312587

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:10:08
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:28:41

US3312587

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:10:08
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:28:46

US3312587

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:10:08
User entered '1'	System	12 Oct 2020 23:28:46

US3312587

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:28:53

US3312587

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:28:53

US3312587

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

[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 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:28:53

US3312587

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered 'VISIT2'	System	12 Oct 2020 23:28:53

US3312587

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	12 Oct 2020 23:29:00

US3312587

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:00

US3312587

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:00

US3312587

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:00

US3312587

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered empty.	System	12 Oct 2020 23:29:00

US3312587

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:00

US3312587

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:00

US3312587

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:00

US3312587

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:00

US3312587

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered empty.	System	12 Oct 2020 23:29:00

US3312587

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:00

US3312587

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered empty.	System	12 Oct 2020 23:29:00

US3312587

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:00

US3312587

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered empty.	System	12 Oct 2020 23:29:00

US3312587

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:00

US3312587

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered empty.	System	12 Oct 2020 23:29:00

US3312587

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	12 Oct 2020 23:29:00

US3312587

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:00

US3312587

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:00

US3312587

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:00

US3312587

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered empty.	System	12 Oct 2020 23:29:00

US3312587

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:00

US3312587

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:00

US3312587

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:00

US3312587

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:00

US3312587

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered empty.	System	12 Oct 2020 23:29:00

US3312587

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:00

US3312587

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered empty.	System	12 Oct 2020 23:29:00

US3312587

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:00

US3312587

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered empty.	System	12 Oct 2020 23:29:00

US3312587

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:00

US3312587

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered empty.	System	12 Oct 2020 23:29:00

US3312587

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:06

US3312587

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:54

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:06

US3312587

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User closed query 'Per CDM: Childbearing potential noted as "Yes" yet pregnancy test not completed. Kindly review and update else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 07:39:16
Query 'Per CDM: Childbearing potential noted as "Yes" yet pregnancy test not completed. Kindly review and update else clarify.' answered with 'Correct as entered. V2 was not performed. No pregnancy test completed.' (Site from DM).	Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:46:02
User opened query 'Per CDM: Childbearing potential noted as "Yes" yet pregnancy test not completed. Kindly review and update else clarify.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 12:30:23
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 23:29:12

US3312587

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:12

US3312587

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:12

US3312587

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:12

US3312587

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:12

US3312587

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:12

US3312587

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:12

US3312587

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered empty.	System	12 Oct 2020 23:29:12

US3312587

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:21

US3312587

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Confirmed COVID-19 (COVID)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:21

US3312587

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

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 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:21

US3312587

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered empty.	System	12 Oct 2020 23:29:21

US3312587

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:21

US3312587

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:21

US3312587

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered empty.	System	12 Oct 2020 23:29:21

US3312587

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:21

US3312587

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered empty.	System	12 Oct 2020 23:29:21

US3312587

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered empty.	System	12 Oct 2020 23:29:21

US3312587

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:26

US3312587

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:54

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:26

US3312587

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:54

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:26

US3312587

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered empty.	System	12 Oct 2020 23:29:26

US3312587

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:12:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:33

US3312587

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:12:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	12 Oct 2020 23:29:33

US3312587

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:12:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:33

US3312587

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:12:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:33

US3312587

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered empty.	System	12 Oct 2020 23:29:33

US3312587

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:12:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	12 Oct 2020 23:29:33

US3312587

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:12:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:33

US3312587

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:29:33

US3312587

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered empty.	System	12 Oct 2020 23:29:33

US3312587

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:02:04
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 23:29:40

US3312587

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered '1'	System	09 Nov 2020 21:02:04
User entered empty.	System	12 Oct 2020 23:29:40

US3312587

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:06:12

US3312587

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:06:12

US3312587

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:06:12

US3312587

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'OCCURRED DURING CONVALESCENT PERIOD.'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:06:12

US3312587

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:06:17

US3312587

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User entered 'I'	System	09 Nov 2020 21:06:17

US3312587

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:07:02

US3312587

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:07:02

US3312587

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:07:02

US3312587

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'OCCURRED DURING CONVALESCENT PERIOD.'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:07:02

US3312587

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:07:07

US3312587

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User entered 'I'	System	09 Nov 2020 21:07:07

US3312587

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:07:35

US3312587

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:07:35

US3312587

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:07:35

US3312587

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'OCCURRED DURING CONVALESCENT PERIOD.'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:07:35

US3312587

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:07:41

US3312587

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User entered 'I'	System	09 Nov 2020 21:07:41

US3312587

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:05

US3312587

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered '06 Nov 2020'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:05

US3312587

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

[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 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:05

US3312587

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User entered 'VISIT3'	System	09 Nov 2020 21:08:05

US3312587

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:25

US3312587

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered '06 Nov 2020'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:25

US3312587

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered '14:13'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:25

US3312587

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User entered '06 Nov 2020 14:13'	System	09 Nov 2020 21:08:25

US3312587

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:25

US3312587

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:25

US3312587

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:25

US3312587

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered '83'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:25

US3312587

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User entered 'bpm'	System	09 Nov 2020 21:08:25

US3312587

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered '14'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:25

US3312587

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User entered 'breaths/min'	System	09 Nov 2020 21:08:25

US3312587

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered '119'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:25

US3312587

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User entered 'mmHg'	System	09 Nov 2020 21:08:25

US3312587

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered '74'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:25

US3312587

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User entered 'mmHg'	System	09 Nov 2020 21:08:25

US3312587

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39

US3312587

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39

US3312587

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:33

US3312587

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:33

US3312587

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:09:36

US3312587

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered '06 Nov 2020'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:09:36

US3312587

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered '14:24'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:09:36

US3312587

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User entered '06 Nov 2020 14:24'	System	09 Nov 2020 21:09:36

US3312587

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:59:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:09:41

US3312587

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User entered 'I'	System	09 Nov 2020 21:09:41

US3312587

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
Data entry locked.	System	09 Sep 2020 21:59:04
User entered 'Day 64'	System	09 Sep 2020 21:59:04

US3312587

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-11-11T12:00:43', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'bbdb9996-c3ed-4c05-b6e3-f2dea924cb68' User entered 'No (N)'	System	11 Nov 2020 18:01:13
	System	11 Nov 2020 18:01:13

US3312587

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-11-11T12:00:50', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'bbdb9996-c3ed-4c05-b6e3-f2dea924cb68'	System	11 Nov 2020 18:01:13
User entered 'No (N)'	System	11 Nov 2020 18:01:13

US3312587

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-11-11T12:00:56', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'bbdb9996-c3ed-4c05-b6e3-f2dea924cb68' User entered '11 Nov 2020 12:00:56'	System	11 Nov 2020 18:01:13
	System	11 Nov 2020 18:01:13

US3312587

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
Data entry locked.	System	09 Sep 2020 21:59:04
User entered '09 Nov 2020 00:01'	System	09 Sep 2020 21:59:04

US3312587

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
Data entry locked.	System	09 Sep 2020 21:59:04
User entered '13 Nov 2020 23:59'	System	09 Sep 2020 21:59:04

US3312587

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
Data entry locked.	System	09 Sep 2020 21:59:04
User entered 'Day 71'	System	09 Sep 2020 21:59:04

US3312587

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-11-16T00:02:03', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '43e40105-f416-4a21-a13a-522d06cb205d' User entered 'No (N)'	System	16 Nov 2020 06:02:11
	System	16 Nov 2020 06:02:11

US3312587

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-11-16T00:02:06', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '43e40105-f416-4a21-a13a-522d06cb205d'	System	16 Nov 2020 06:02:11
User entered 'No (N)'	System	16 Nov 2020 06:02:11

US3312587

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-11-16T00:02:09', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '43e40105-f416-4a21-a13a-522d06cb205d' User entered '16 Nov 2020 00:02:09'	System	16 Nov 2020 06:02:11
	System	16 Nov 2020 06:02:11

US3312587

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
Data entry locked.	System	09 Sep 2020 21:59:04
User entered '16 Nov 2020 00:01'	System	09 Sep 2020 21:59:04

US3312587

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:10:01
Data entry locked.	System	09 Sep 2020 21:59:04
User entered '20 Nov 2020 23:59'	System	09 Sep 2020 21:59:04

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you had 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-11-23T19:43:52', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '0fcfa51d-8518-4e16-859d-2dfb17ab6b22'	System	24 Nov 2020 01:44:07
User entered 'No (N)'	System	24 Nov 2020 01:44:07

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you been exposed to someone with known SARS-CoV-2 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-11-23T19:44:01', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '0fcfa51d-8518-4e16-859d-2dfb17ab6b22'	System	24 Nov 2020 01:44:07
User entered 'No (N)'	System	24 Nov 2020 01:44:07

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-11-23T19:44:04', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '0fcfa51d-8518-4e16-859d-2dfb17ab6b22'	System	24 Nov 2020 01:44:07
User entered '23 Nov 2020 19:44:04'	System	24 Nov 2020 01:44:07

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you had 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-11-29T12:00:16', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'dc09f18a-9906-4777-803a-23512e7f2753'	System	29 Nov 2020 18:00:26
User entered 'No (N)'	System	29 Nov 2020 18:00:26

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you been exposed to someone with known SARS-CoV-2 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-11-29T12:00:20', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'dc09f18a-9906-4777-803a-23512e7f2753'	System	29 Nov 2020 18:00:26
User entered 'No (N)'	System	29 Nov 2020 18:00:26

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-11-29T12:00:23', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'dc09f18a-9906-4777-803a-23512e7f2753'	System	29 Nov 2020 18:00:26
User entered '29 Nov 2020 12:00:23'	System	29 Nov 2020 18:00:26

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you had 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-12-06T12:09:40', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'd52bf1ce-16d4-4060-9dac-02ba16d448bd' User entered 'No (N)'	System	06 Dec 2020 18:09:52
	System	06 Dec 2020 18:09:52

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you been exposed to someone with known SARS-CoV-2 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-12-06T12:09:43', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'd52bf1ce-16d4-4060-9dac-02ba16d448bd' User entered 'No (N)'	System	06 Dec 2020 18:09:52
	System	06 Dec 2020 18:09:52

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-12-06T12:09:46', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'd52bf1ce-16d4-4060-9dac-02ba16d448bd' User entered '06 Dec 2020 12:09:46'	System	06 Dec 2020 18:09:52
	System	06 Dec 2020 18:09:52

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you had 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-12-14T14:32:39', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'e6558ace-8734-415c-82b8-cc164e133e8d' User entered 'No (N)'	System	14 Dec 2020 20:32:45
	System	14 Dec 2020 20:32:45

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you been exposed to someone with known SARS-CoV-2 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-12-14T14:32:41', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'e6558ace-8734-415c-82b8-cc164e133e8d' User entered 'No (N)'	System	14 Dec 2020 20:32:45
	System	14 Dec 2020 20:32:45

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-12-14T14:32:43', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'e6558ace-8734-415c-82b8-cc164e133e8d' User entered '14 Dec 2020 14:32:43'	System	14 Dec 2020 20:32:45
	System	14 Dec 2020 20:32:45

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you had 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-12-22T12:19:50', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'ef85c95e-e1a7-43e5-8fb4-0cea79d324e9'	System	22 Dec 2020 18:19:58
User entered 'No (N)'	System	22 Dec 2020 18:19:58

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you been exposed to someone with known SARS-CoV-2 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-12-22T12:19:53', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'ef85c95e-e1a7-43e5-8fb4-0cea79d324e9'	System	22 Dec 2020 18:19:58
User entered 'No (N)'	System	22 Dec 2020 18:19:58

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-12-22T12:19:55', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'ef85c95e-e1a7-43e5-8fb4-0cea79d324e9' User entered '22 Dec 2020 12:19:55'	System	22 Dec 2020 18:19:58
	System	22 Dec 2020 18:19:58

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you had 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-12-25T02:43:31', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'd2754df4-1116-45ee-8a16-dfc4469397e2'	System	25 Dec 2020 08:43:37
User entered 'No (N)'	System	25 Dec 2020 08:43:37

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you been exposed to someone with known SARS-CoV-2 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-12-25T02:43:33', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'd2754df4-1116-45ee-8a16-dfc4469397e2'	System	25 Dec 2020 08:43:37
User entered 'No (N)'	System	25 Dec 2020 08:43:37

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2020-12-25T02:43:35', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'd2754df4-1116-45ee-8a16-dfc4469397e2' User entered '25 Dec 2020 02:43:35'	System	25 Dec 2020 08:43:37
	System	25 Dec 2020 08:43:37

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you had 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-01-01T09:25:24', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'b8bd0191-8d4b-49cd-b081-753d20633dcb' User entered 'No (N)'	System	01 Jan 2021 15:25:32

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you been exposed to someone with known SARS-CoV-2 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-01-01T09:25:26', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'b8bd0191-8d4b-49cd-b081-753d20633dcb' User entered 'No (N)'	System	01 Jan 2021 15:25:32

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-01-01T09:25:30', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'b8bd0191-8d4b-49cd-b081-753d20633dcb' User entered '01 Jan 2021 09:25:30'	System	01 Jan 2021 15:25:32
	System	01 Jan 2021 15:25:32

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you had 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-01-10T12:00:37', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '2ab56d48-e0aa-46e5-88ba-6b48dbbc0d28' User entered 'No (N)'	System	10 Jan 2021 18:00:57
	System	10 Jan 2021 18:00:57

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you been exposed to someone with known SARS-CoV-2 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-01-10T12:00:41', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '2ab56d48-e0aa-46e5-88ba-6b48dbbc0d28'	System	10 Jan 2021 18:00:57
User entered 'No (N)'	System	10 Jan 2021 18:00:57

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-01-10T12:00:47', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '2ab56d48-e0aa-46e5-88ba-6b48dbbc0d28' User entered '10 Jan 2021 12:00:47'	System	10 Jan 2021 18:00:57

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you had 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-01-18T15:21:57', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '1a79e9b2-8afe-4491-b150-f54e312fd8e0' User entered 'No (N)'	System	18 Jan 2021 21:22:06
	System	18 Jan 2021 21:22:06

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you been exposed to someone with known SARS-CoV-2 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-01-18T15:21:59', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '1a79e9b2-8afe-4491-b150-f54e312fd8e0'	System	18 Jan 2021 21:22:06
User entered 'No (N)'	System	18 Jan 2021 21:22:06

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-01-18T15:22:02', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '1a79e9b2-8afe-4491-b150-f54e312fd8e0' User entered '18 Jan 2021 15:22:02'	System	18 Jan 2021 21:22:06
	System	18 Jan 2021 21:22:06

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you had 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-01-24T12:00:49', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '539e067e-3217-48f2-88ab-ec95cab35120' User entered 'No (N)'	System	24 Jan 2021 18:01:52

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you been exposed to someone with known SARS-CoV-2 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-01-24T12:00:52', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '539e067e-3217-48f2-88ab-ec95cab35120' User entered 'No (N)'	System	24 Jan 2021 18:01:52

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-01-24T12:00:55', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '539e067e-3217-48f2-88ab-ec95cab35120' User entered '24 Jan 2021 12:00:55'	System	24 Jan 2021 18:01:52
	System	24 Jan 2021 18:01:52

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you had 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-01-31T12:11:06', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '5f193602-f8ee-42fb-a21d-967e3c876ebf' User entered 'No (N)'	System	31 Jan 2021 18:11:19
	System	31 Jan 2021 18:11:19

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you been exposed to someone with known SARS-CoV-2 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-01-31T12:11:10', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '5f193602-f8ee-42fb-a21d-967e3c876ebf' User entered 'No (N)'	System	31 Jan 2021 18:11:19

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-01-31T12:11:13', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '5f193602-f8ee-42fb-a21d-967e3c876ebf' User entered '31 Jan 2021 12:11:13'	System	31 Jan 2021 18:11:19
	System	31 Jan 2021 18:11:19

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you had 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-02-05T09:20:41', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '0997622b-4765-448b-a5c9-4ca0a9bcf007' User entered 'No (N)'	System	05 Feb 2021 15:20:48
	System	05 Feb 2021 15:20:48

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you been exposed to someone with known SARS-CoV-2 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-02-05T09:20:43', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '0997622b-4765-448b-a5c9-4ca0a9bcf007'	System	05 Feb 2021 15:20:48
User entered 'No (N)'	System	05 Feb 2021 15:20:48

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-02-05T09:20:46', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '0997622b-4765-448b-a5c9-4ca0a9bcf007' User entered '05 Feb 2021 09:20:46'	System	05 Feb 2021 15:20:48
	System	05 Feb 2021 15:20:48

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you had 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-02-14T12:00:23', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'ea11ee30-39da-46f7-984e-17bab70e76e6' User entered 'No (N)'	System	14 Feb 2021 18:01:15
	System	14 Feb 2021 18:01:15

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you been exposed to someone with known SARS-CoV-2 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-02-14T12:00:26', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'ea11ee30-39da-46f7-984e-17bab70e76e6'	System	14 Feb 2021 18:01:15
User entered 'No (N)'	System	14 Feb 2021 18:01:15

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-02-14T12:00:29', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'ea11ee30-39da-46f7-984e-17bab70e76e6' User entered '14 Feb 2021 12:00:29'	System	14 Feb 2021 18:01:15
	System	14 Feb 2021 18:01:15

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you had 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-02-19T16:39:22', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '851384cc-6a52-47f6-8b05-7eb2c4cc13f2' User entered 'No (N)'	System	19 Feb 2021 22:39:32
	System	19 Feb 2021 22:39:32

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you been exposed to someone with known SARS-CoV-2 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-02-19T16:39:24', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '851384cc-6a52-47f6-8b05-7eb2c4cc13f2' User entered 'No (N)'	System	19 Feb 2021 22:39:32

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-02-19T16:39:27', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '851384cc-6a52-47f6-8b05-7eb2c4cc13f2'	System	19 Feb 2021 22:39:32
User entered '19 Feb 2021 16:39:27'	System	19 Feb 2021 22:39:32

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you had 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-03-01T17:59:38-06:00', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'e54bc403-358f-439a-a4b9-798d86c34d15'	System	01 Mar 2021 23:59:46
User entered 'No (N)'	System	01 Mar 2021 23:59:46

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

Have you been exposed to someone with known SARS-CoV-2 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-03-01T17:59:40-06:00', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'e54bc403-358f-439a-a4b9-798d86c34d15'	System	01 Mar 2021 23:59:46
User entered 'No (N)'	System	01 Mar 2021 23:59:46

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-03-01T17:59:43-06:00', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'e54bc403-358f-439a-a4b9-798d86c34d15'	System	01 Mar 2021 23:59:46
User entered '01 Mar 2021 17:59:43'	System	01 Mar 2021 23:59:46

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you had 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-03-07T12:00:48-06:00', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '4523db49-7bde-41ec-91ba-35b2a0f673ad'	System	07 Mar 2021 18:01:24
User entered 'No (N)'	System	07 Mar 2021 18:01:24

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

Have you been exposed to someone with known SARS-CoV-2 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-03-07T12:00:50-06:00', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '4523db49-7bde-41ec-91ba-35b2a0f673ad'	System	07 Mar 2021 18:01:24
User entered 'No (N)'	System	07 Mar 2021 18:01:24

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-03-07T12:00:54-06:00', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '4523db49-7bde-41ec-91ba-35b2a0f673ad' User entered '07 Mar 2021 12:00:54'	System	07 Mar 2021 18:01:24
	System	07 Mar 2021 18:01:24

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you had 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-03-14T12:30:16-05:00', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '5e699b02-e513-4078-a684-c7d64e437e39'	System	14 Mar 2021 17:30:25
User entered 'No (N)'	System	14 Mar 2021 17:30:25

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you been exposed to someone with known SARS-CoV-2 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-03-14T12:30:18-05:00', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '5e699b02-e513-4078-a684-c7d64e437e39'	System	14 Mar 2021 17:30:25
User entered 'No (N)'	System	14 Mar 2021 17:30:25

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-03-14T12:30:21-05:00', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '5e699b02-e513-4078-a684-c7d64e437e39'	System	14 Mar 2021 17:30:25
User entered '14 Mar 2021 12:30:21'	System	14 Mar 2021 17:30:25

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you had 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-03-21T12:02:14-05:00', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '3625204e-45e4-4cd1-9724-7af920e89d91'	System	21 Mar 2021 17:04:43
User entered 'No (N)'	System	21 Mar 2021 17:04:43

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you been exposed to someone with known SARS-CoV-2 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-03-21T12:02:17-05:00', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '3625204e-45e4-4cd1-9724-7af920e89d91'	System	21 Mar 2021 17:04:43
User entered 'No (N)'	System	21 Mar 2021 17:04:43

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-03-21T12:02:20-05:00', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '3625204e-45e4-4cd1-9724-7af920e89d91'	System	21 Mar 2021 17:04:43
User entered '21 Mar 2021 12:02:20'	System	21 Mar 2021 17:04:43

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you had 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-03-28T12:00:36-05:00', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '0b410c8a-d40f-4bb7-9f3a-c108458fb456'	System	28 Mar 2021 17:00:53
User entered 'No (N)'	System	28 Mar 2021 17:00:53

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you been exposed to someone with known SARS-CoV-2 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-03-28T12:00:38-05:00', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '0b410c8a-d40f-4bb7-9f3a-c108458fb456'	System	28 Mar 2021 17:00:53
User entered 'No (N)'	System	28 Mar 2021 17:00:53

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-03-28T12:00:39-05:00', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '0b410c8a-d40f-4bb7-9f3a-c108458fb456'	System	28 Mar 2021 17:00:53
User entered '28 Mar 2021 12:00:39'	System	28 Mar 2021 17:00:53

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you had 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-04-04T12:37:49-05:00', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '48b35883-d7f2-4e58-8378-1c13b710927c' User entered 'No (N)'	System	04 Apr 2021 17:37:57
	System	04 Apr 2021 17:37:57

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you been exposed to someone with known SARS-CoV-2 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-04-04T12:37:50-05:00', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '48b35883-d7f2-4e58-8378-1c13b710927c' User entered 'No (N)'	System	04 Apr 2021 17:37:57
	System	04 Apr 2021 17:37:57

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-04-04T12:37:53-05:00', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '48b35883-d7f2-4e58-8378-1c13b710927c'	System	04 Apr 2021 17:37:57
User entered '04 Apr 2021 12:37:53'	System	04 Apr 2021 17:37:57

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you had 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-04-11T12:03:47-05:00', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'fecd17f3-daf9-4bdd-8bf2-13a259debc0f' User entered 'No (N)'	System	11 Apr 2021 17:05:29
	System	11 Apr 2021 17:05:29

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you been exposed to someone with known SARS-CoV-2 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-04-11T12:03:49-05:00', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'fecd17f3-daf9-4bdd-8bf2-13a259debc0f' User entered 'No (N)'	System	11 Apr 2021 17:05:29
	System	11 Apr 2021 17:05:29

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-04-11T12:03:52-05:00', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'fecd17f3-daf9-4bdd-8bf2-13a259debc0f' User entered '11 Apr 2021 12:03:52'	System	11 Apr 2021 17:05:29
	System	11 Apr 2021 17:05:29

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you had 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-04-19T17:59:15-05:00', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'bbedef33-694e-4605-9732-bd0808780beb' User entered 'No (N)'	System	19 Apr 2021 22:59:24

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you been exposed to someone with known SARS-CoV-2 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-04-19T17:59:19-05:00', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'bbedef33-694e-4605-9732-bd0808780beb' User entered 'No (N)'	System	19 Apr 2021 22:59:24
	System	19 Apr 2021 22:59:24

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-04-19T17:59:22-05:00', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'bbedef33-694e-4605-9732-bd0808780beb' User entered '19 Apr 2021 17:59:22'	System	19 Apr 2021 22:59:24
	System	19 Apr 2021 22:59:24

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you had 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-04-25T12:00:39-05:00', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '4b59cc64-2cd4-412a-b5bf-e14e6ec87a7d' User entered 'No (N)'	System	25 Apr 2021 17:01:36
	System	25 Apr 2021 17:01:36

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you been exposed to someone with known SARS-CoV-2 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-04-25T12:00:46-05:00', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '4b59cc64-2cd4-412a-b5bf-e14e6ec87a7d'	System	25 Apr 2021 17:01:36
User entered 'No (N)'	System	25 Apr 2021 17:01:36

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-04-25T12:00:52-05:00', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '4b59cc64-2cd4-412a-b5bf-e14e6ec87a7d'	System	25 Apr 2021 17:01:36
User entered '25 Apr 2021 12:00:52'	System	25 Apr 2021 17:01:36

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you had 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-04-30T13:03:17-05:00', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'f1b98588-2a8a-40b3-98d5-db028f688e9e'	System	30 Apr 2021 18:03:25
User entered 'No (N)'	System	30 Apr 2021 18:03:25

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Have you been exposed to someone with known SARS-CoV-2 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 (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-04-30T13:03:19-05:00', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'f1b98588-2a8a-40b3-98d5-db028f688e9e'	System	30 Apr 2021 18:03:25
User entered 'No (N)'	System	30 Apr 2021 18:03:25

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-04-30T13:03:22-05:00', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: 'f1b98588-2a8a-40b3-98d5-db028f688e9e'	System	30 Apr 2021 18:03:25
User entered '30 Apr 2021 13:03:22'	System	30 Apr 2021 18:03:25

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 06:52:42

US3312587

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:52:42
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 06:52:42

US3312587

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:12:54

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:47:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-03-01T17:59:51-06:00', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '380989af-4272-433f-b945-56cc4c6a58c3'	System	02 Mar 2021 00:00:05
User entered 'No (N)'	System	02 Mar 2021 00:00:05

US3312587

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:12:54

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:47:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09353800-D6AF-444F-89BE-8AEE611133F6)', Time: '2021-03-01T17:59:56-06:00', User OID: 'PatientReportedOutcome (US3312587)', ODM File OID: '380989af-4272-433f-b945-56cc4c6a58c3' User entered '01 Mar 2021 17:59:56'	System	02 Mar 2021 00:00:05
	System	02 Mar 2021 00:00:05

US3312587

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 16:30:15

US3312587

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '02 Dec 2020'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 16:30:15

US3312587

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 16:30:15

US3312587

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 16:30:15

US3312587

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 16:30:18

US3312587

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:00:39
User entered 'I'	System	04 Dec 2020 16:30:18

US3312587

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:31:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 14:56:18

US3312587

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:31:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '05 Jan 2021'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 14:56:18

US3312587

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:31:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 14:56:18

US3312587

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:31:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 14:56:18

US3312587

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:31:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 14:56:22

US3312587

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:31:39
User entered 'I'	System	07 Jan 2021 14:56:22

US3312587

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:31:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 22:56:58

US3312587

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:31:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 22:56:58

US3312587

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:31:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 22:56:58

US3312587

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:31:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 22:56:58

US3312587

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:31:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 22:57:00

US3312587

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:31:39
User entered 'I'	System	02 Feb 2021 22:57:00

US3312587

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:31:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:44:03

US3312587

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:31:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '05 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:44:03

US3312587

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:31:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:44:03

US3312587

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:31:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:44:03

US3312587

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:31:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:44:06

US3312587

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:31:39
User entered 'I'	System	09 Mar 2021 17:44:06

US3312587

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:41:41

US3312587

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '06 Apr 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:41:41

US3312587

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:41:41

US3312587

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:19
User entered 'VISIT4'	System	06 Apr 2021 18:41:41

US3312587

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:41:46

US3312587

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:25
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:41:46

US3312587

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:25
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:41:46

US3312587

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:19
User entered empty.	System	06 Apr 2021 18:41:46

US3312587

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:25
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:41:46

US3312587

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:25
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:41:46

US3312587

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:25
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:41:46

US3312587

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:25
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:41:46

US3312587

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:19
User entered empty.	System	06 Apr 2021 18:41:46

US3312587

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:25
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:41:46

US3312587

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:19
User entered empty.	System	06 Apr 2021 18:41:46

US3312587

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:25
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:41:46

US3312587

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:19
User entered empty.	System	06 Apr 2021 18:41:46

US3312587

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:25
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:41:46

US3312587

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:19
User entered empty.	System	06 Apr 2021 18:41:46

US3312587

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:19

US3312587

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:19

US3312587

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:41:50

US3312587

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:54

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:41:50

US3312587

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:42:08

US3312587

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '06 Apr 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:42:08

US3312587

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '13:34'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:42:08

US3312587

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:19
User entered '06 Apr 2021 13:34'	System	06 Apr 2021 18:42:08

US3312587

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:42:14

US3312587

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:19
User entered 'I'	System	06 Apr 2021 18:42:14

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:12:54

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:40:05
User entered '07 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 23:33:28

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:12:54

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:40:05
User entered '10:00'	(b) (4), (b) (6)	12 Oct 2020 23:33:28

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:12:54

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:43
User entered '07 Oct 2020 10:00'	System	12 Oct 2020 23:33:28

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:12:54

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:40:05
User entered 'Safety Call (Safety Call)'	(b) (4), (b) (6)	12 Oct 2020 23:33:28

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:12:54

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:40:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 23:33:28

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:12:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:34:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:12:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '03 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:34:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:12:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:34:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:12:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 16:56:52
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 23:34:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:12:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
User entered '%'	System	18 Dec 2020 16:56:52
User entered empty.	System	12 Oct 2020 23:34:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:12:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 16:56:52
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 23:34:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:12:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:34:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:12:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:34:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:12:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:34:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:12:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:34:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:12:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 23:36:11
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Oct 2020 23:34:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:12:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:34:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:12:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:34:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:12:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:34:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:12:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:34:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:12:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:34:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:12:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:34:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:12:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:34:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:12:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:34:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:12:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:34:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:12:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:34:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:12:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:34:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:12:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Day 2 (Day 2)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:34:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:12:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '04 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:34:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:12:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:34:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:12:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 16:56:52
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 23:34:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:12:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
User entered '%'	System	18 Dec 2020 16:56:52
User entered empty.	System	12 Oct 2020 23:34:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:12:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 16:56:52
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 23:34:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:12:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:34:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:12:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:34:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:12:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:34:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:12:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:34:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:12:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 23:36:11
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Oct 2020 23:34:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:12:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:34:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:12:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:34:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:12:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:34:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:12:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:34:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:12:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:34:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:12:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:34:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:12:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:34:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:12:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:34:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:12:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:34:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:12:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:34:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:12:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:34:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:12:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:35:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:12:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '05 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:35:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:12:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:35:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:12:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered missing code ND - Not Done; reason for	(b) (4)	18 Dec 2020 16:56:52
change Data Entry Error	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 23:35:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:12:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
User entered '%'	System	18 Dec 2020 16:56:52
User entered empty.	System	12 Oct 2020 23:35:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:12:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 16:56:52
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 23:35:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:12:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:35:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:12:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:35:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:12:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:35:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:12:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:35:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:12:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:35:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:12:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:35:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:12:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:35:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:12:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:35:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:12:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:35:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:12:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:35:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:12:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:35:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:12:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:35:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:12:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:35:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:12:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:35:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:12:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:35:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:12:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:35:49

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:12:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:37:40

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:12:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '06 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:37:40

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:12:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:37:40

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:12:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 16:56:52
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 23:37:40

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:12:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
User entered '%'	System	18 Dec 2020 16:56:52
User entered empty.	System	12 Oct 2020 23:37:40

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:12:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '100.6' F	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:37:40

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:12:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:37:40

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:12:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:37:40

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:12:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:37:40

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:12:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:37:40

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:12:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:37:40

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:12:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:37:40

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:12:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:37:40

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:12:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:37:40

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:12:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:37:40

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:12:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:37:40

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:12:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:37:40

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:12:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:37:40

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:12:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:37:40

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:12:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:37:40

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:12:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:37:40

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:12:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:37:40

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:12:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:39:03

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:12:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:39:03

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:12:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:39:03

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:12:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '99'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:39:03

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:12:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
User entered '%'	System	12 Oct 2020 23:39:03

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:12:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '98.5' F	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:39:03

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:12:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:39:03

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:12:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:39:03

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:12:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:39:03

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:12:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:39:03

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:12:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:39:03

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:12:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:39:03

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:12:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:39:03

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:12:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:39:03

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:12:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:39:03

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:12:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:39:03

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:12:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:39:03

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:12:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:39:03

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:12:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:39:03

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:12:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:39:03

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:12:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:39:03

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:12:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:39:03

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:12:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:40:14

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:12:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '08 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:40:14

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:12:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:40:14

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:12:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '99'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:40:14

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:12:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
User entered '%'	System	12 Oct 2020 23:40:14

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:12:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:40:14

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:12:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:40:14

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:12:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:40:14

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:12:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:40:14

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:12:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:40:14

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:12:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:40:14

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:12:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:40:14

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:12:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:40:14

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:12:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:40:14

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:12:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:40:14

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:12:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:40:14

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:12:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:40:14

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:12:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:40:14

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:12:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:40:14

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:12:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:40:14

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:12:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:40:14

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:12:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:40:14

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:12:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:41:11

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:12:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '09 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:41:11

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:12:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:41:11

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:12:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '97'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:41:11

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:12:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
User entered '%'	System	12 Oct 2020 23:41:11

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:12:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '97.6' F	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:41:11

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:12:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:41:11

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:12:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:41:11

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:12:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:41:11

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:12:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:41:11

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:12:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:41:11

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:12:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:41:11

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:12:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:41:11

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:12:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:41:11

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:12:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:41:11

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:12:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:41:11

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:12:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:41:11

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:12:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:41:11

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:12:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:41:11

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:12:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:41:11

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:12:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:41:11

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:12:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:41:11

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:12:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Day 8 (Day 8)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:42:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:12:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '10 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:42:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:12:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:42:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:12:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '97'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:42:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:12:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
User entered '%'	System	12 Oct 2020 23:42:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:12:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '97.6' F	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:42:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:12:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:42:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:12:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:42:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:12:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:42:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:12:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:42:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:12:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:42:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:12:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:42:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:12:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:42:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:12:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:42:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:12:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:42:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:12:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:42:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:12:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:42:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:12:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:42:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:12:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:42:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:12:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:42:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:12:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:42:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:12:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:42:17

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:12:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Day 9 (Day 9)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:43:07

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:12:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '11 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:43:07

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:12:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:43:07

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:12:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '97'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:43:07

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:12:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
User entered '%'	System	12 Oct 2020 23:43:07

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:12:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '97.1' F	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:43:07

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:12:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:43:07

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:12:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:43:07

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:12:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:43:07

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:12:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:43:07

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:12:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:43:07

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:12:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:43:07

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:12:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:43:07

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:12:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:43:07

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:12:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:43:07

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:12:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:43:07

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:12:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:43:07

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:12:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:43:07

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:12:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:43:07

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:12:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:43:07

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:12:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:43:07

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:12:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:43:07

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:12:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Day 10 (Day 10)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:53:25

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:12:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '12 Oct 2020'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 16:53:25
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:12:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:53:25

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:12:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '98'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:53:25

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:12:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
User entered '%'	System	21 Oct 2020 16:53:25

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:12:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '98.5' F	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 16:53:25
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:12:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 16:53:25
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:12:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 16:53:25
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:12:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:53:25

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:12:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:53:25

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:12:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:53:25

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:12:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 16:53:25
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:12:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 16:53:25
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:12:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:53:25

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:12:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:53:25

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:12:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 16:53:25
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:12:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:53:25

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:12:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:53:25

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:12:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 16:53:25
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:12:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 16:53:25
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:12:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 16:53:25
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:12:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:53:25

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:12:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Day 11 (Day 11)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:56:00

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:12:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '13 Oct 2020'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 16:56:00
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:12:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:56:00

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:12:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '95'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:56:00

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:12:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
User entered '%'	System	21 Oct 2020 16:56:00

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:12:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '97.7' F	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:56:00

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:12:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 16:56:00
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:12:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 16:56:00
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:12:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 16:56:00
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:12:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4)	21 Oct 2020 16:56:00
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:12:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:56:00

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:12:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 16:56:00
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:12:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 16:56:00
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:12:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4)	21 Oct 2020 16:56:00
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:12:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:56:00

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:12:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 16:56:00
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:12:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:56:00

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:12:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:56:00

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:12:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 16:56:00
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:12:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 16:56:00
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:12:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 16:56:00
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:12:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 16:56:00
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:12:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Day 12 (Day 12)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:57:33

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:12:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '14 Oct 2020'	(b) (4)	21 Oct 2020 16:57:33
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:12:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '0'	(b) (4)	21 Oct 2020 16:57:33
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:12:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '97'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:57:33

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:12:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
User entered '%'	System	21 Oct 2020 16:57:33

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:12:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '97.1' F	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 16:57:33
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:12:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 16:57:33
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:12:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 16:57:33
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:12:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 16:57:33
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:12:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:57:33

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:12:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:57:33

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:12:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 16:57:33
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:12:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 16:57:33
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:12:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4)	21 Oct 2020 16:57:33
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:12:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 16:57:33
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:12:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 16:57:33
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:12:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 16:57:33
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:12:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:57:33

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:12:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 16:57:33
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:12:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:57:33

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:12:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:57:33

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:12:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 16:57:33
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:12:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Day 13 (Day 13)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:59:08

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:12:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '15 Oct 2020'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 16:59:08
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:12:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:59:08

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:12:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '96'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:59:08

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:12:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
User entered '%'	System	21 Oct 2020 16:59:08

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:12:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '98.1' F	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 16:59:08
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:12:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 16:59:08
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:12:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:59:08

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:12:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 16:59:08
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:12:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:59:08

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:12:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:59:08

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:12:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:59:08

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:12:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 16:59:08
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:12:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 16:59:08
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:12:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 16:59:08
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:12:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 16:59:08
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:12:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 16:59:08
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:12:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:59:08

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:12:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 16:59:08
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:12:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 16:59:08
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:12:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:59:08

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:12:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 16:59:08

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:12:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Day 14 (Day 14)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:00:31

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:12:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '16 Oct 2020'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 17:00:31
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:12:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:00:31

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:12:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '96'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:00:31

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:12:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
User entered '%'	System	21 Oct 2020 17:00:31

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:12:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '97.1' F	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:00:31

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:12:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:00:31
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:12:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4)	21 Oct 2020 17:00:31
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:12:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:00:31
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:12:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:00:31
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:12:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4)	21 Oct 2020 17:00:31
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:12:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:00:31
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:12:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:00:31
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:12:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:00:31

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:12:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:00:31
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:12:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:00:31

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:12:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:00:31
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:12:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:00:31

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:12:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:00:31
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:12:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:00:31
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:12:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:00:31
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:12:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:00:31

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:12:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Day 15 (Day 15)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:01:44

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:12:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '17 Oct 2020'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 17:01:44
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:12:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '0'	(b) (4)	21 Oct 2020 17:01:44
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:12:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '96'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:01:44

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:12:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
User entered '%'	System	21 Oct 2020 17:01:44

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:12:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '97.0' F	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 17:01:44
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:12:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:01:44

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:12:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:01:44
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:12:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 17:01:44
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:12:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:01:44

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:12:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4)	21 Oct 2020 17:01:44
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:12:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:01:44

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:12:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:01:44
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:12:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4)	21 Oct 2020 17:01:44
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:12:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:01:44

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:12:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:01:44

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:12:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:01:44

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:12:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:01:44

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:12:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:01:44
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:12:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:01:44
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:12:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:01:44

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:12:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:01:44

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:12:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Day 16 (Day 16)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:02:58

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:12:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '18 Oct 2020' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 17:03:11
User entered '12 Oct 2020'	Karol Moore (b) (4)	21 Oct 2020 17:02:58
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:12:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:02:58

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:12:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '97'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:02:58

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:12:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
User entered '%'	System	21 Oct 2020 17:02:58

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:12:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '96.4' F	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:02:58

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:12:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:02:58
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:12:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:02:58
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:12:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:02:58
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:12:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:02:58

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:12:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4)	21 Oct 2020 17:02:58
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:12:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 17:02:58
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:12:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:02:58
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:12:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:02:58
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:12:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:02:58

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:12:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:02:58
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:12:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:02:58

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:12:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:02:58

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:12:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:02:58
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:12:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 17:02:58
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:12:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:02:58

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:12:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:02:58

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:12:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Day 17 (Day 17)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:04:20

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:12:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '19 Oct 2020'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 17:04:20
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:12:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:04:20

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:12:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '97'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:04:20

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:12:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
User entered '%'	System	21 Oct 2020 17:04:20

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:12:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '96.8' F	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:04:20

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:12:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:04:20
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:12:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:04:20
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:12:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:04:20
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:12:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:04:20
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:12:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:04:20
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:12:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:04:20
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:12:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:04:20
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:12:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:04:20

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:12:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:04:20

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:12:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:04:20

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:12:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:04:20
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:12:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:04:20

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:12:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:04:20
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:12:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:04:20
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:12:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:04:20
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:12:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:04:20

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:12:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Day 18 (Day 18)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:05:09

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:12:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User closed query 'Per CDM: Please confirm no additional records require entry pass 20OCT2020 or update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:08:22
Query 'Per CDM: Please confirm no additional records require entry pass 20OCT2020 or update accordingly.' answered with 'confirmed covid symptoms ended this day 20Oct2020' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 20:10:03
User opened query 'Per CDM: Please confirm no additional records require entry pass 20OCT2020 or update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 03:16:54
User entered '20 Oct 2020'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:05:09

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:12:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '0'	(b) (4)	21 Oct 2020 17:05:09
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:12:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '96'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:05:09

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:12:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
User entered '%'	System	21 Oct 2020 17:05:09

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:12:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '96.8' F	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:05:09

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:12:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:05:09
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:12:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:05:09
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:12:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:05:09
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:12:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:05:09
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:12:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 17:05:09
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:12:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:05:09

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:12:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:05:09
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:12:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:05:09
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:12:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:05:09
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:12:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:05:09
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:12:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 17:05:09
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:12:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:05:09

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:12:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:05:09
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:12:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:05:09
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:12:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:05:09

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:12:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:49
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:53:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'None (None)'	(b) (4)	21 Oct 2020 17:05:09
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:12:54

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:18
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:43:32

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:12:54

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:18
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:43:32

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:12:54

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:18
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 18:12:49
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 23:43:40
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	12 Oct 2020 23:43:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 23:43:32

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:12:54

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:18
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:43:32

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:12:54

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:18
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	12 Oct 2020 23:43:32

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:12:54

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:18
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:43:32

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:12:54

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:18
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:43:32

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:12:54

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:18
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:43:32

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:12:54

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:18
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:43:32

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:12:54

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:18:55
User entered 'I'	System	12 Oct 2020 23:43:32

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:12:54

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:12

US3312587

Folder: Covid-19 Assessment 07 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:12:54

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:19:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:56
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'No (N)'	(b) (4) Kelly Moen (b) (4) (b) (4)	10 Dec 2020 22:40:17

US3312587

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:12:54

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	12 Oct 2020 23:46:23

US3312587

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:12:54

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:07:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:46:23

US3312587

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:12:54

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:07:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '09 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:46:23

US3312587

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:12:54

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	12 Oct 2020 23:46:23

US3312587

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:12:54

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:07:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:46:23

US3312587

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:12:54

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:07:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '11 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:46:23

US3312587

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:12:54

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	12 Oct 2020 23:46:23

US3312587

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:12:54

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:07:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Oct 2020 17:20:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 17:20:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Karol Moore (b) (4)	21 Oct 2020 17:20:11
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	12 Oct 2020 23:46:23
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 23:46:23

US3312587

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:12:54

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:07:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '13 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:09:47
User entered '15 Oct 2020' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:20:11
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 23:46:23

US3312587

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:12:54

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	12 Oct 2020 23:46:23

US3312587

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:12:54

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:07:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Oct 2020 17:20:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 17:20:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Karol Moore (b) (4)	21 Oct 2020 17:20:11
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	12 Oct 2020 23:46:23
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 23:46:23

US3312587

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:12:54

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:07:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '15 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:09:47
User entered '20 Oct 2020' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:20:11
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 23:46:23

US3312587

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:12:54

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	12 Oct 2020 23:46:23

US3312587

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:12:54

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:07:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User closed query 'Per CDM: Please advise if additional Saliva samples were collected pass 21OCT2020 and if so, update accordingly' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 14:43:10
Query 'Per CDM: Please advise if additional Saliva samples were collected pass 21OCT2020 and if so, update accordingly' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	10 Nov 2020 20:14:13
User opened query 'Per CDM: Please advise if additional Saliva samples were collected pass 21OCT2020 and if so, update accordingly' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 03:17:39
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 17:20:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 17:20:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:20:11
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 23:46:23
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 23:46:23

US3312587

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:12:54

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:07:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '21 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:09:47
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 23:46:23

US3312587

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:12:54

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	12 Oct 2020 23:46:23

US3312587

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:12:54

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:07:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 20:14:07
User closed query 'Data is required. Please complete.' (Site from System).	Karol Moore (b) (4)	22 Oct 2020 08:52:20
Query 'Data is required. Please complete.' answered with 'will answer at d21' (Site from System).	(b) (4)	21 Oct 2020 17:20:48
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 23:46:23
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 23:46:23

US3312587

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:12:54

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:07:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '28 Oct 2020' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 20:14:07
User entered empty.	Karol Moore (b) (4)	12 Oct 2020 23:46:23
	(b) (4)	
	(b) (4), (b) (6)	

US3312587

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:12:54

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	12 Oct 2020 23:46:23

US3312587

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:12:54

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:07:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 20:14:07
User closed query 'Data is required. Please complete.' (Site from System).	Karol Moore (b) (4)	22 Oct 2020 08:52:23
Query 'Data is required. Please complete.' answered with 'will answer at d28' (Site from System).	(b) (4)	21 Oct 2020 17:20:56
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 23:46:23
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 23:46:23

US3312587

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:12:54

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:07:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '03 Nov 2020' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 20:14:07
User entered empty.	Karol Moore (b) (4)	12 Oct 2020 23:46:23
	(b) (4)	
	(b) (4), (b) (6)	

US3312587

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:05:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:27

US3312587

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:05:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:27

US3312587

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:05:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:44:27

US3312587

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:05
User entered 'SICKD1'	System	12 Oct 2020 23:44:27

US3312587

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:05:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:45:46

US3312587

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:05:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:45:46

US3312587

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:05:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '13:35'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:45:46

US3312587

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:05
User entered '07 Oct 2020 13:35'	System	12 Oct 2020 23:45:46

US3312587

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:05:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '67' in	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:45:46
DataPoint set to visible.	System	12 Oct 2020 23:44:27

US3312587

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:05:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '159.5' lb	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:45:46
DataPoint set to visible.	System	12 Oct 2020 23:44:27

US3312587

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:05:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '98.5' F	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:45:46

US3312587

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:05:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:45:46

US3312587

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:05:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:45:46

US3312587

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:05:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '87'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:45:46

US3312587

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:05
User entered 'bpm'	System	12 Oct 2020 23:45:46

US3312587

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:05:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '14'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:45:46

US3312587

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:05
User entered 'breaths/min'	System	12 Oct 2020 23:45:46

US3312587

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:05:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '120'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:45:46

US3312587

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:05
User entered 'mmHg'	System	12 Oct 2020 23:45:46

US3312587

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:05:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '87'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:45:46

US3312587

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:05
User entered 'mmHg'	System	12 Oct 2020 23:45:46

US3312587

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:05

US3312587

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:05

US3312587

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:05:50
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:45:55

US3312587

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:05:50
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:45:55

US3312587

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:12:54

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:06:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:46:04

US3312587

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:12:54

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:06:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:46:04

US3312587

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:06:12
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'Yes (Y)'	(b) (4)	10 Nov 2020 20:11:10
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:06:12
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered '03 Nov 2020'	(b) (4)	
	Karol Moore (b) (4)	10 Nov 2020 20:11:10
	(b) (4)	

US3312587

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:06:12
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'Clinic (Clinic)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Nov 2020 20:11:10

US3312587

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
User entered 'SICKD28'	System	10 Nov 2020 20:11:10

US3312587

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:06:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'Yes (Y)'	(b) (4)	10 Nov 2020 20:11:57
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:06:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered '03 Nov 2020'	(b) (4)	
	Karol Moore (b) (4)	10 Nov 2020 20:11:57
	(b) (4)	

US3312587

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:06:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered '10:46'	(b) (4)	
	Karol Moore (b) (4)	10 Nov 2020 20:11:57
	(b) (4)	

US3312587

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
User entered '03 Nov 2020 10:46'	System	10 Nov 2020 20:11:57

US3312587

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:06:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered missing code ND - Not Done.	(b) (4)	
	Karol Moore (b) (4)	10 Nov 2020 20:11:57
	(b) (4)	
DataPoint set to visible.	System	10 Nov 2020 20:11:10

US3312587

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:06:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered missing code ND - Not Done.	(b) (4)	
	Karol Moore (b) (4)	10 Nov 2020 20:11:57
	(b) (4)	
DataPoint set to visible.	System	10 Nov 2020 20:11:10

US3312587

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:06:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered '98.3' F	(b) (4)	
	Karol Moore (b) (4)	10 Nov 2020 20:11:57
	(b) (4)	

US3312587

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:06:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'Oral (Oral)'	(b) (4)	10 Nov 2020 20:11:57
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:06:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered empty.	(b) (4)	10 Nov 2020 20:11:57
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:06:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered '75'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Nov 2020 20:11:57

US3312587

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
User entered 'bpm'	System	10 Nov 2020 20:11:57

US3312587

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:06:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered '12'	(b) (4)	
	Karol Moore (b) (4)	10 Nov 2020 20:11:57
	(b) (4)	

US3312587

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
User entered 'breaths/min'	System	10 Nov 2020 20:11:57

US3312587

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:06:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered '115'	(b) (4)	
	Karol Moore (b) (4)	10 Nov 2020 20:11:57
	(b) (4)	

US3312587

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
User entered 'mmHg'	System	10 Nov 2020 20:11:57

US3312587

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:06:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered '76'	(b) (4)	
	Karol Moore (b) (4)	10 Nov 2020 20:11:57
	(b) (4)	

US3312587

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
User entered 'mmHg'	System	10 Nov 2020 20:11:57

US3312587

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24

US3312587

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24

US3312587

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:06:42
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'Yes (Y)'	(b) (4)	
	Karol Moore (b) (4)	10 Nov 2020 20:12:04
	(b) (4)	

US3312587

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:06:42
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered '03 Nov 2020'	(b) (4)	
	Karol Moore (b) (4)	10 Nov 2020 20:12:04
	(b) (4)	

US3312587

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:12:54

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:06:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Nov 2020 20:12:11

US3312587

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:12:54

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:06:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered '03 Nov 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Nov 2020 20:12:11

US3312587

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

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:35:39

US3312587

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

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '06 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:35:39

US3312587

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

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

[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 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:35:39

US3312587

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

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered 'UNBLND_DECIDE'	System	10 Feb 2021 15:35:39

US3312587

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

Form: Unblinding

Generated On: 11 Aug 2021 22:12:54

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '06 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:38:25

US3312587

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

Form: Unblinding

Generated On: 11 Aug 2021 22:12:54

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:45:57
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:54:50

US3312587

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

Form: Unblinding

Generated On: 11 Aug 2021 22:12:54

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:38:25

US3312587

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

Form: Unblinding

Generated On: 11 Aug 2021 22:12:54

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:45:57
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:54:50

US3312587

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

Form: Unblinding

Generated On: 11 Aug 2021 22:12:54

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '06 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:38:25

US3312587

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

Form: Unblinding

Generated On: 11 Aug 2021 22:12:54

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:38:25

US3312587

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

Form: Unblinding

Generated On: 11 Aug 2021 22:12:54

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:38:25

US3312587

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

Form: Unblinding

Generated On: 11 Aug 2021 22:12:54

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Not Administered (NA)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:38:25

US3312587

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

Form: Unblinding

Generated On: 11 Aug 2021 22:12:54

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:38:25

US3312587

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

Form: Unblinding

Generated On: 11 Aug 2021 22:12:54

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered '1'	System	10 Feb 2021 15:38:25

US3312587

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

Form: Unblinding

Generated On: 11 Aug 2021 22:12:54

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered 'I'	System	10 Feb 2021 15:38:25

US3312587

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:12:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:40:11

US3312587

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:12:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:40:11

US3312587

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:12:54

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered empty.	System	10 Feb 2021 15:40:11
DataPoint set to visible.	System	10 Feb 2021 15:38:25

US3312587

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:12:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:40:11

US3312587

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:12:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:40:11

US3312587

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:12:54

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered empty.	System	10 Feb 2021 15:40:11
DataPoint set to visible.	System	10 Feb 2021 15:38:25

US3312587

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	10 Feb 2021 15:40:11

US3312587

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:40:11

US3312587

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '06 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:40:11

US3312587

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '11:58'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:40:11

US3312587

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered '06 Feb 2021 11:58'	System	10 Feb 2021 15:40:11

US3312587

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '98.5' F	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:40:11

US3312587

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:40:11

US3312587

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:40:11

US3312587

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '68'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:40:11

US3312587

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered 'bpm'	System	10 Feb 2021 15:40:11

US3312587

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '14'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:40:11

US3312587

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered 'breaths/min'	System	10 Feb 2021 15:40:11

US3312587

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '113'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:40:11

US3312587

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered 'mmHg'	System	10 Feb 2021 15:40:11

US3312587

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '72'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:40:11

US3312587

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered 'mmHg'	System	10 Feb 2021 15:40:11

US3312587

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:12:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:40:11

US3312587

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:12:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:40:11

US3312587

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:12:54

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered empty.	System	10 Feb 2021 15:40:11
DataPoint set to visible.	System	10 Feb 2021 15:38:25

US3312587

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	10 Feb 2021 15:40:58

US3312587

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:40:58

US3312587

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '06 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:40:58

US3312587

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '13:39'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:40:58

US3312587

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered '06 Feb 2021 13:39'	System	10 Feb 2021 15:40:58

US3312587

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '98.5' F	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:40:58

US3312587

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:40:58

US3312587

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:40:58

US3312587

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '69'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:40:58

US3312587

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered 'bpm'	System	10 Feb 2021 15:40:58

US3312587

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '12'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:40:58

US3312587

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered 'breaths/min'	System	10 Feb 2021 15:40:58

US3312587

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '117'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:40:58

US3312587

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered 'mmHg'	System	10 Feb 2021 15:40:58

US3312587

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '66'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:40:58

US3312587

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered 'mmHg'	System	10 Feb 2021 15:40:58

US3312587

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:41:13

US3312587

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:54

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '06 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:41:13

US3312587

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:42:56

US3312587

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '06 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:42:56

US3312587

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:42:56

US3312587

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:42:56

US3312587

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:42:56

US3312587

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:42:56

US3312587

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:42:56

US3312587

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered empty.	System	10 Feb 2021 15:42:56

US3312587

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

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:44:12

US3312587

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

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:44:12

US3312587

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

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

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 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:44:12

US3312587

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

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered 'mRNA-1273'	System	10 Feb 2021 15:44:12
DataPoint set to visible.	System	10 Feb 2021 15:38:25

US3312587

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

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '06 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:44:12

US3312587

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

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '13:08'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:44:12

US3312587

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

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered '06 Feb 2021 13:08'	System	10 Feb 2021 15:44:12

US3312587

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

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:44:12

US3312587

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

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered 'ONCE'	System	10 Feb 2021 15:44:12

US3312587

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

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered 'INTRAMUSCULAR'	System	10 Feb 2021 15:44:12

US3312587

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:39:02

US3312587

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '06 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:39:02

US3312587

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '11:29'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:39:02

US3312587

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered '06 Feb 2021 11:29'	System	10 Feb 2021 15:39:02

US3312587

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:12:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:39:14

US3312587

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '06 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:39:14

US3312587

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:12:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '11:28'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:39:14

US3312587

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered '06 Feb 2021 11:28'	System	10 Feb 2021 15:39:14

US3312587

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

Form: Continuing

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:39:23

US3312587

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

Form: Continuing

Generated On: 11 Aug 2021 22:12:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:37
User entered 'I'	System	10 Feb 2021 15:39:23

US3312587

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:24:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 14:57:48

US3312587

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:24:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 14:57:48

US3312587

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:24:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 14:57:48

US3312587

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:24:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 14:57:48

US3312587

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:24:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 14:57:56

US3312587

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:24:32
User entered 'I'	System	26 Feb 2021 14:57:56

US3312587

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:54

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:24:32
User entered '1'	System	26 Feb 2021 14:57:56
DataPoint set to visible.	System	26 Feb 2021 14:57:56

US3312587

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:48:08

US3312587

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '06 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:48:08

US3312587

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:48:08

US3312587

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User entered 'OLD29'	System	09 Mar 2021 17:48:08

US3312587

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	09 Mar 2021 17:50:11

US3312587

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:50:11

US3312587

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '06 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:50:11

US3312587

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '11:21'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:50:11

US3312587

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User entered '06 Mar 2021 11:21'	System	09 Mar 2021 17:50:11

US3312587

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '98.5' F	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:50:11

US3312587

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:50:11

US3312587

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:50:11

US3312587

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '71'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:50:11

US3312587

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User entered 'bpm'	System	09 Mar 2021 17:50:11

US3312587

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '14'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:50:11

US3312587

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User entered 'breaths/min'	System	09 Mar 2021 17:50:11

US3312587

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '117'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:50:11

US3312587

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User entered 'mmHg'	System	09 Mar 2021 17:50:11

US3312587

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '67'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:50:11

US3312587

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User entered 'mmHg'	System	09 Mar 2021 17:50:11

US3312587

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	09 Mar 2021 17:50:11

US3312587

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:50:11

US3312587

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '06 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:50:11

US3312587

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '12:50'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:50:11

US3312587

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User entered '06 Mar 2021 12:50'	System	09 Mar 2021 17:50:11

US3312587

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:50:11

US3312587

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:50:11

US3312587

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:50:11

US3312587

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '94'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:50:11

US3312587

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User entered 'bpm'	System	09 Mar 2021 17:50:11

US3312587

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '12'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:50:11

US3312587

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User entered 'breaths/min'	System	09 Mar 2021 17:50:11

US3312587

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '108'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:50:11

US3312587

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User entered 'mmHg'	System	09 Mar 2021 17:50:11

US3312587

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
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)	10 Mar 2021 12:01:01
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 'CONFIRMED CORRECT AS ENTERED. NCS NOT AN AE. DIASTOLIC LOW BP NOT ON TOXICITY TABLE.' (Site from System).	(b) (4), (b) (6)	09 Mar 2021 17:50:48
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).		09 Mar 2021 17:50:11
User entered '58'	(b) (4), (b) (6)	09 Mar 2021 17:50:11

US3312587

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User entered 'mmHg'	System	09 Mar 2021 17:50:11

US3312587

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:51:00

US3312587

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:54

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '06 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:51:00

US3312587

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:51:26

US3312587

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '06 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:51:26

US3312587

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:51:26

US3312587

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:51:26

US3312587

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User closed query 'Per CDM: "Was FSH sample collected?" is answered as NO, however date and time are collected. If date and time belongs to FSH then please consider changing answer from No to Yes. If date and time belongs to Pregnancy test, then please remove date and time. Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 11:47:12
Query 'Per CDM: "Was FSH sample collected?" is answered as NO, however date and time are collected. If date and time belongs to FSH then please consider changing answer from No to Yes. If date and time belongs to Pregnancy test, then please remove date and time. Thank you!' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	19 Mar 2021 17:21:24
User opened query 'Per CDM: "Was FSH sample collected?" is answered as NO, however date and time are collected. If date and time belongs to FSH then please consider changing answer from No to Yes. If date and time belongs to Pregnancy test, then please remove date and time. Thank you!' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 14:00:03
User entered 'No (N)'	(b) (4), (b) (6)	09 Mar 2021 17:51:26

US3312587

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty; reason for change Data Entry Error	(b) (4)	19 Mar 2021 17:21:18
User entered '06 Mar 2021'	Karol Moore (b) (4)	09 Mar 2021 17:51:26
	(b) (4)	
	(b) (4), (b) (6)	

US3312587

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty; reason for change Data Entry Error	(b) (4)	19 Mar 2021 17:21:18
User entered '12:02'	Karol Moore (b) (4)	09 Mar 2021 17:51:26
	(b) (4)	
	(b) (4), (b) (6)	

US3312587

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User entered empty.	System	19 Mar 2021 17:21:18
User entered '06 Mar 2021 12:02'	System	09 Mar 2021 17:51:26

US3312587

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:51:41

US3312587

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:51:41

US3312587

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:51:41

US3312587

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User entered 'mRNA-1273'	System	09 Mar 2021 17:51:41
DataPoint set to visible.	System	26 Feb 2021 14:57:56

US3312587

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '06 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:51:41

US3312587

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '12:19'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:51:41

US3312587

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User entered '06 Mar 2021 12:19'	System	09 Mar 2021 17:51:41

US3312587

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:51:41

US3312587

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User entered 'ONCE'	System	09 Mar 2021 17:51:41

US3312587

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:54

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User entered 'INTRAMUSCULAR'	System	09 Mar 2021 17:51:41

US3312587

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:51:50

US3312587

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:37:38
User entered 'I'	System	09 Mar 2021 17:51:50

US3312587

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:24:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:24:05

US3312587

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:24:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:24:05

US3312587

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:24:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:24:05

US3312587

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:24:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:24:05

US3312587

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:24:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:23:55

US3312587

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:24:32
User entered 'I'	System	16 Mar 2021 15:23:55

US3312587

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:42:28

US3312587

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '06 Apr 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:42:28

US3312587

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:42:28

US3312587

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:54

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	06 Apr 2021 18:42:28

US3312587

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:42:35

US3312587

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:42:35

US3312587

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:42:35

US3312587

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 18:42:35

US3312587

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:42:35

US3312587

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:42:35

US3312587

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:42:35

US3312587

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:42:35

US3312587

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 18:42:35

US3312587

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:42:35

US3312587

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 18:42:35

US3312587

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:42:35

US3312587

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 18:42:35

US3312587

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:42:35

US3312587

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 18:42:35

US3312587

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:42:41

US3312587

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:54

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:42:41

US3312587

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:42:48

US3312587

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '06 Apr 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:42:48

US3312587

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '13:34'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:42:48

US3312587

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
User entered '06 Apr 2021 13:34'	System	06 Apr 2021 18:42:48

US3312587

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:12:54

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:26:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:39
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:08:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:46:32

US3312587

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:12:54

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:08:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:16
User entered 'USA-US300-2020-mRNA-1273-P301000004'	System	13 Oct 2020 15:32:11
User entered 'New'	(b) (4), (b) (6)	13 Oct 2020 15:32:11

US3312587

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:12:54

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:08:48
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 23:52:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 23:52:28
Data point term sent to Coder	System	12 Oct 2020 23:50:51
User entered 'symptomatic covid 19'	(b) (4), (b) (6)	12 Oct 2020 23:50:17

US3312587

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:12:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:08:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:50:17

US3312587

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:12:54

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:08:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:50:17

US3312587

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:12:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:08:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:50:17

US3312587

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:12:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:08:48
User closed query 'PV Query: Since the subject started experiencing COVID-19 symptoms prior to 07 Oct 2019, please consider updating the event onset date to the start date of symptoms.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 21:31:53
Query 'PV Query: Since the subject started experiencing COVID-19 symptoms prior to 07 Oct 2019, please consider updating the event onset date to the start date of symptoms.' answered with 'updated per source' (Site from Safety).	Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:08:03
User entered '03 Oct 2020' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:07:57
User opened query 'PV Query: Since the subject started experiencing COVID-19 symptoms prior to 07 Oct 2019, please consider updating the event onset date to the start date of symptoms.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 17:16:09
User entered '07 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 23:50:17

US3312587

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:08:48
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:50:17

US3312587

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:12:54

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 23:50:17

US3312587

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:12:54

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:08:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 20:14:41
User entered 'Yes (Y)'	Karol Moore (b) (4)	12 Oct 2020 23:50:17
	(b) (4)	
	(b) (4), (b) (6)	

US3312587

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:12:54

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:08:48
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:22:30
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' answered with 'UPDATED' (Site from Safety).	Karol Moore (b) (4) (b) (4)	10 Nov 2020 20:14:49
User entered '20 Oct 2020' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	10 Nov 2020 20:14:41
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 20:03:10
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 23:50:17

US3312587

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:08:48
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:50:17

US3312587

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:12:54

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 18:43:23
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 17:15:40
User entered empty.	System	12 Oct 2020 23:50:17

US3312587

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:12:54

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:08:48
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:50:17

US3312587

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:12:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:08:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:50:17

US3312587

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:12:54

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:08:48
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:50:17

US3312587

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:12:54

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:08:48
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:50:17

US3312587

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:12:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:08:48
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:50:17

US3312587

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:12:54

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:08:48
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:50:17

US3312587

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:12:54

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:08:48
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:50:17

US3312587

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:12:54

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:08:48
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:50:17

US3312587

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:12:54

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:08:48
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:50:17

US3312587

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:12:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:08:48
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:50:17

US3312587

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:12:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:08:48
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:50:17

US3312587

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:12:54

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:08:48
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:50:17

US3312587

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:12:54

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:08:48
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:50:17

US3312587

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:12:54

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:08:48
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:50:17

US3312587

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:12:54

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:08:48
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 12:43:51
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'updated to SARS COV 19' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 19:11:15
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	26 Oct 2020 18:57:16
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6)	12 Oct 2020 23:50:17

US3312587

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:12:54

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:08:48
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:50:17

US3312587

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:12:54

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:08:48
User entered 'I'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:50:17

US3312587

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:12:54

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:08:48
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:50:17

US3312587

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:12:54

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:08:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	10 Nov 2020 20:14:41
Data Entry Error	Karol Moore (b) (4)	
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 21:33:02
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'will update when resolved' (Site from Safety).	Karol Moore (b) (4)	21 Oct 2020 17:07:46
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 17:15:52
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	12 Oct 2020 23:50:17

US3312587

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:12:54

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:08:48
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:50:17

US3312587

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:12:54

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:08:48
User closed query 'PV Query: Please clarify whether the subject had an occupational risk, location and living/circumstances risk, or a possible opportunity of exposure to SARS-COV-2.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:43:20
Query 'PV Query: Please clarify whether the subject had an occupational risk, location and living/circumstances risk, or a possible opportunity of exposure to SARS-COV-2.' answered with 'SUBJECT RESIDES IN COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION' (Site from Safety).	Karol Moore (b) (4) (b) (4)	18 Nov 2020 16:59:35
User opened query 'PV Query: Please clarify whether the subject had an occupational risk, location and living/circumstances risk, or a possible opportunity of exposure to SARS-COV-2.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 17:15:21
User entered 'Subject called with mild to moderate symptoms, illness visit completed same day. Positive results received today 12Oct2020-Subject has not see additional healthcare providers other than site, O2 sats upper 90's, and symptoms resolving. Took OTC meds.'	(b) (4), (b) (6)	12 Oct 2020 23:50:17

US3312587

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:12:54

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Oct 2020 23:50:17

US3312587

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:12:54

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 23:50:17

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:12:54

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:26:14
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:36:35

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:12:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN SODIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Sep 2020 00:06:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 00:06:41
Data point term sent to Coder	System	29 Sep 2020 17:37:31
User entered 'NAPROXEN SODIUM'	Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:37:06

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:12:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	29 Sep 2020 17:37:06
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:12:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'RIGHT CARPAL TUNNEL'	Karol Moore (b) (4)	29 Sep 2020 17:37:06
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:12:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered '220'	Karol Moore (b) (4)	29 Sep 2020 17:37:06
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:12:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	29 Sep 2020 17:37:06
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:12:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	29 Sep 2020 17:37:06
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:12:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'as needed (PRN)'	Karol Moore (b) (4)	29 Sep 2020 17:37:06
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:12:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	29 Sep 2020 17:37:06
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:12:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	29 Sep 2020 17:37:06
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:12:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	29 Sep 2020 17:37:06
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'UN UNK 2010'	Karol Moore (b) (4)	29 Sep 2020 17:37:06
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:12:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	29 Sep 2020 17:37:06
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:12:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	29 Sep 2020 17:37:06
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:12:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	29 Sep 2020 17:37:06
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:12:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	29 Sep 2020 17:37:06
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:12:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 17:37:06

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:12:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 17:37:06

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:12:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 17:37:06

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:12:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Sep 2020 23:03:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 23:03:39
Data point term sent to Coder	System	29 Sep 2020 17:38:32
User entered 'EXCEDRIN (ACETAMINOPHEN/ASPIRIN/CAFFEINE)'	Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:37:59

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:12:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	29 Sep 2020 17:37:59
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:12:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'OCCASIONAL MIGRAINE'	Karol Moore (b) (4)	29 Sep 2020 17:37:59
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:12:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered '250/250/65'	Karol Moore (b) (4)	29 Sep 2020 17:37:59
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:12:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	29 Sep 2020 17:37:59
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:12:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	29 Sep 2020 17:37:59
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:12:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'as needed (PRN)'	Karol Moore (b) (4)	29 Sep 2020 17:37:59
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:12:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	29 Sep 2020 17:37:59
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:12:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	29 Sep 2020 17:37:59
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:12:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	29 Sep 2020 17:37:59
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'UN UNK 2003'	Karol Moore (b) (4)	29 Sep 2020 17:37:59
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:12:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	29 Sep 2020 17:37:59
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:12:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	29 Sep 2020 17:37:59
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:12:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	29 Sep 2020 17:37:59
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:12:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	29 Sep 2020 17:37:59
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:12:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 17:37:59

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:12:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 17:37:59

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:12:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 17:37:59

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:12:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Sep 2020 17:39:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 17:39:34
Data point term sent to Coder	System	29 Sep 2020 17:38:33
User entered 'LEVOTHYROXINE'	Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:38:29

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:12:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	29 Sep 2020 17:38:29
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:12:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'HYPOTHYROIDISM'	Karol Moore (b) (4)	29 Sep 2020 17:38:29
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:12:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered '50'	Karol Moore (b) (4)	29 Sep 2020 17:38:29
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:12:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'ug (ug)'	Karol Moore (b) (4)	29 Sep 2020 17:38:29
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:12:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	29 Sep 2020 17:38:29
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:12:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'once daily (QD)'	Karol Moore (b) (4)	29 Sep 2020 17:38:29
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:12:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	29 Sep 2020 17:38:29
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:12:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	29 Sep 2020 17:38:29
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:12:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	29 Sep 2020 17:38:29
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'UN UNK 2016'	Karol Moore (b) (4)	29 Sep 2020 17:38:29
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:12:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	29 Sep 2020 17:38:29
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:12:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	29 Sep 2020 17:38:29
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:12:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	29 Sep 2020 17:38:29
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:12:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	29 Sep 2020 17:38:29
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:12:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 17:38:29

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:12:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 17:38:29

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:12:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Sep 2020 17:38:29

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:12:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: SUMATRIPTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Sep 2020 01:59:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 01:59:41
Data point term sent to Coder	System	29 Sep 2020 17:39:34
User entered 'SUMATRIPTAN'	Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:38:52

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:12:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	29 Sep 2020 17:38:52
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:12:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'OCCASIONAL MIGRAINE'	Karol Moore (b) (4)	29 Sep 2020 17:38:52
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:12:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered '100'	Karol Moore (b) (4)	29 Sep 2020 17:38:52
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:12:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	29 Sep 2020 17:38:52
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:12:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	29 Sep 2020 17:38:52
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:12:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'as needed (PRN)'	Karol Moore (b) (4)	29 Sep 2020 17:38:52
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:12:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	29 Sep 2020 17:38:52
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:12:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	29 Sep 2020 17:38:52
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:12:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	29 Sep 2020 17:38:52
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'UN UNK 2003'	Karol Moore (b) (4)	29 Sep 2020 17:38:52
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:12:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	29 Sep 2020 17:38:52
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:12:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	29 Sep 2020 17:38:52
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:12:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	29 Sep 2020 17:38:52
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:12:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	29 Sep 2020 17:38:52
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:12:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 17:38:52

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:12:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 17:38:52

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:12:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 17:38:52

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:12:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: AMFETAMINE ASPARTATE;AMFETAMINE SULFATE;DEXAMFETAMINE SACCHARATE;DEXAMFETAMINE SULFATE, PRODUCTSYNONYM: ADDERALL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 17:40:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 17:40:39
Data point term sent to Coder	System	29 Sep 2020 17:39:36
User entered 'ADDERALL'	Karol Moore (b) (4)	29 Sep 2020 17:39:18

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:12:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	29 Sep 2020 17:39:18
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:12:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'Attention deficit hyperactivity disorder'	Karol Moore (b) (4)	29 Sep 2020 17:39:18
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:12:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered '10'	Karol Moore (b) (4)	29 Sep 2020 17:39:18
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:12:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	29 Sep 2020 17:39:18
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:12:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	29 Sep 2020 17:39:18
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:12:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'twice daily (BID)'	Karol Moore (b) (4)	29 Sep 2020 17:39:18
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:12:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	29 Sep 2020 17:39:18
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:12:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	29 Sep 2020 17:39:18
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:12:54

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	29 Sep 2020 17:39:18
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'UN UNK 2014'	Karol Moore (b) (4)	29 Sep 2020 17:39:18
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:12:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	29 Sep 2020 17:39:18
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:12:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	29 Sep 2020 17:39:18
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:12:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	29 Sep 2020 17:39:18
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:12:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	29 Sep 2020 17:39:18
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:12:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Sep 2020 17:39:18

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:12:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 17:39:18

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:12:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Sep 2020 17:39:18

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:12:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;FERROUS FUMARATE;NORETHISTERONE ACETATE, PRODUCTSYNONYM: JUNEL FE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 14:29:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 14:29:56
Data point term sent to Coder	System	11 Mar 2021 21:17:01
Coding entries removed.	(b) (4), (b) (6)	11 Mar 2021 21:16:17
User entered 'JUNEL FE (Norethindrone acetate 1mg, ethinyl estradiol 20mcg)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Mar 2021 21:16:17
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;NORETHISTERONE ACETATE, PRODUCTSYNONYM: JUNEL FE 1/20 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 18:11:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 18:11:43
Data point term sent to Coder	System	29 Sep 2020 17:40:37
User entered 'Junel Fe 1/20'	Karol Moore (b) (4)	29 Sep 2020 17:39:56

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:12:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:39:56

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:12:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'BIRTH CONTROL'	Karol Moore (b) (4)	29 Sep 2020 17:39:56

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:12:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered '1' reason for change: Data Entry Error	(b) (4)	30 Mar 2021 20:09:12
User entered '1/20' reason for change: Data Entry Error	Monica Atwood (b) (4)	19 Mar 2021 21:39:44
User entered '1'	Karol Moore (b) (4)	29 Sep 2020 17:39:56
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:12:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'tablet (TABLET)' reason for change: Data Entry Error	(b) (4) Monica Atwood (b) (4)	30 Mar 2021 20:09:12
User closed query 'Per CDM RQ: Please note the dosage should be added in the appropriate field and separated by "/", and dose unit entered in "other" if necessary. Please reconcile, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 11:47:48
Query 'Per CDM RQ: Please note the dosage should be added in the appropriate field and separated by "/", and dose unit entered in "other" if necessary. Please reconcile, thank you.' answered with 'UPDATED PER QUERY RESOLUTION' (Site from DM).	Karol Moore (b) (4) (b) (4)	19 Mar 2021 21:40:02
User entered 'Other (OTHER)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	19 Mar 2021 21:39:44
User opened query 'Per CDM RQ: Please note the dosage should be added in the appropriate field and separated by "/", and dose unit entered in "other" if necessary. Please reconcile, thank you.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 14:31:54
User closed query 'Per DM CLR Requery-Response noted as 'updated',however,no update has been made to the dose unit .Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable else please clarify.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 13:21:50
Query 'Per DM CLR Requery-Response noted as 'updated',however,no update has been made to the dose unit .Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable else please clarify.' answered with 'CORRECT AS ENTERED. DOSE UNIT IS TABLET. SEE "NAME OF MEDICATION" TO SEE DOSE ELEMENTS' (Site from DM).	Karol Moore (b) (4) (b) (4)	17 Mar 2021 23:07:36

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:12:54

[Dose unit](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR Requery-Response noted as 'updated',however,no update has been made to the dose unit .Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable else please clarify.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 10:03:48
User closed query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 10:03:48
Query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' answered with 'UPDATED.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 21:16:24
User opened query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 10:47:22
User entered 'tablet (TABLET)'	Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:39:56

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:12:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User closed query 'Per DM CLR: Please review and verify if the UNIT can be more appropriately recorded as UG as it is one of the pre-listed options. If yes, please update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:01:46
Query 'Per DM CLR: Please review and verify if the UNIT can be more appropriately recorded as UG as it is one of the pre-listed options. If yes, please update accordingly. ' answered with 'updated' (Site from DM).	Monica Atwood (b) (4) (b) (4)	30 Mar 2021 20:09:43
User entered empty; reason for change Data Entry Error	Monica Atwood (b) (4) (b) (4)	30 Mar 2021 20:09:12
User opened query 'Per DM CLR: Please review and verify if the UNIT can be more appropriately recorded as UG as it is one of the pre-listed options. If yes, please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 08:16:27
User entered 'MG/MCG' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	19 Mar 2021 21:39:44
User entered empty.	Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:39:56

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:12:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'once daily (QD)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:39:56

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:12:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:39:56

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:12:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'Oral (ORAL)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:39:56

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:12:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:39:56

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'UN UNK 2015'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:39:56

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:12:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:39:56

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:12:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:48:59
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:39:56

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:12:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	10 Feb 2021 15:49:11
User entered '21 Dec 2020' reason for change: Data Entry Error	System	10 Feb 2021 15:49:11
User opened query 'Future date has been entered. Please correct.' (Site from System).	(b) (4), (b) (6)	10 Feb 2021 15:48:59
User entered '21 Dec 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 15:48:59
User entered empty.	Karol Moore (b) (4)	29 Sep 2020 17:39:56
	(b) (4)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:12:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:39:56

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:12:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:09
User entered '1'	System	29 Sep 2020 17:39:56

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:12:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:09
User entered '1'	System	29 Sep 2020 17:39:56

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:12:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:09
User entered '804 (804)'	System	29 Sep 2020 17:39:56

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:12:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:12
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 10:19:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 10:19:29
Data point term sent to Coder	System	12 Oct 2020 23:13:14
User entered 'acetaminophen 250mg/aspirin 250mg/caffeine 65mg'	(b) (4), (b) (6)	12 Oct 2020 23:12:33

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:12:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:12
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:12:33

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:12:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:12
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'symptomatic covid-19'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:12:33

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:12:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:12
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered '2'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:12:33

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:12:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:12
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:12:33

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:12:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:12
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:12:33

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:12:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:12
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:12:33

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:12:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:12
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:12:33

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:12:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:12
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:12:33

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:12:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:12
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:12:33

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:12
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered '05 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:12:33

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:12:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:12
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:12:33

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:12:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:12
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:12:33

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:12:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:12
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered '19 Oct 2020' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 17:06:11
User entered '06 Oct 2020'	Karol Moore (b) (4)	12 Oct 2020 23:12:33
	(b) (4)	
	(b) (4), (b) (6)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:12:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:12
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:12:33

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:12:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:12
User entered empty.	System	12 Oct 2020 23:12:33

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:12:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:12
User entered empty.	System	12 Oct 2020 23:12:33

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:12:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:12
User entered empty.	System	12 Oct 2020 23:12:33

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:12:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 15:04:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 15:04:29
Data point term sent to Coder	System	12 Oct 2020 23:51:52
User entered 'ibuprofen'	(b) (4), (b) (6)	12 Oct 2020 23:51:32

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:12:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:51:32

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:12:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'symptomatic covid 19'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:51:32

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:12:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered '200'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:51:32

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:12:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:51:32

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:12:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:51:32

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:12:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:51:32

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:12:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:51:32

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:12:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:51:32

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:12:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:51:32

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered '08 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:51:32

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:12:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:51:32

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:12:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 17:05:57
User entered 'Yes (Y)'	Karol Moore (b) (4)	12 Oct 2020 23:51:32
	(b) (4)	
	(b) (4), (b) (6)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:12:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered '13 Oct 2020' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 17:05:57
User entered empty.	Karol Moore (b) (4)	12 Oct 2020 23:51:32
	(b) (4)	
	(b) (4), (b) (6)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:12:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:51:32

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:12:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:15
User entered empty.	System	12 Oct 2020 23:51:32

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:12:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:15
User entered empty.	System	12 Oct 2020 23:51:32

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:12:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:15
User entered empty.	System	12 Oct 2020 23:51:32

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:12:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PHENYLEPHRINE HYDROCHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 05:43:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 05:43:24
Data point term sent to Coder	System	12 Oct 2020 23:52:53
User entered 'Phenylephrine Hydrochloride'	(b) (4), (b) (6)	12 Oct 2020 23:52:13

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:12:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:52:13

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:12:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'Symptomatic Covid 19'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:52:13

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:12:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered '10'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:52:13

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:12:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:52:13

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:12:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:52:13

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:12:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:52:13

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:12:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:52:13

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:12:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:52:13

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:12:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:52:13

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered '08 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:52:13

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:12:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:52:13

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:12:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 17:06:33
User entered 'Yes (Y)'	Karol Moore (b) (4)	12 Oct 2020 23:52:13
	(b) (4)	
	(b) (4), (b) (6)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:12:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered '13 Oct 2020' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 17:06:33
User entered empty.	Karol Moore (b) (4)	12 Oct 2020 23:52:13
	(b) (4)	
	(b) (4), (b) (6)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:12:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:52:13

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:12:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:19
User entered empty.	System	12 Oct 2020 23:52:13

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:12:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:19
User entered empty.	System	12 Oct 2020 23:52:13

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:12:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:19
User entered empty.	System	12 Oct 2020 23:52:13

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:12:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: TRIAMCINOLONE ACETONIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 05:50:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 05:50:26
Data point term sent to Coder	System	12 Oct 2020 23:53:53
User entered 'Triamcinolone acetonide'	(b) (4), (b) (6)	12 Oct 2020 23:53:16

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:12:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:53:16

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:12:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'symptomatic covid 19'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:53:16

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:12:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered '55'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:53:16

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:12:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'ug (ug)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:53:16

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:12:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:53:16

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:12:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:53:16

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:12:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:53:16

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:12:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	12 Oct 2020 23:53:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Oct 2020 23:53:24
User entered 'Nasal (NASAL)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 23:53:24
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 23:53:16
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 23:53:16

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:12:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:53:16

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:12:54

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered '11 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:53:16

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:12:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:53:16

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:12:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 17:06:48
User entered 'Yes (Y)'	Karol Moore (b) (4)	12 Oct 2020 23:53:16
	(b) (4)	
	(b) (4), (b) (6)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:12:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered '20 Oct 2020' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 17:06:48
User entered empty.	Karol Moore (b) (4)	12 Oct 2020 23:53:16
	(b) (4)	
	(b) (4), (b) (6)	

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:12:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:53:16

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:12:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:20
User entered empty.	System	12 Oct 2020 23:53:16

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:12:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:20
User entered empty.	System	12 Oct 2020 23:53:16

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:12:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:20
User entered empty.	System	12 Oct 2020 23:53:16

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:12:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:24
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 21:13:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 21:13:36
Data point term sent to Coder	System	09 Nov 2020 21:12:37
User entered 'SEASONAL INFLUENZA VACCINATION'	(b) (4), (b) (6)	09 Nov 2020 21:11:53

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:12:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:24
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:11:53

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:12:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:24
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'INFLUENZA PROPHYLAXIS'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:11:53

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:12:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:24
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'I'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:11:53

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:12:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:24
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:11:53

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:12:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:24
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'INJECTION'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:11:53

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:12:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:24
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:11:53

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:12:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:24
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:11:53

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:12:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:24
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:11:53

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:12:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:24
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:11:53

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:24
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:11:53

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:12:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:24
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:11:53

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:12:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:24
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:11:53

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:12:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:24
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:11:53

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:12:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:24
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:11:53

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:12:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:24
User entered empty.	System	09 Nov 2020 21:11:53

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:12:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:24
User entered empty.	System	09 Nov 2020 21:11:53

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:12:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:34:24
User entered empty.	System	09 Nov 2020 21:11:53

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:12:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAVAGINAL CONTRACEPTIVES, PRODUCT: ETHINYLESTRADIOL;ETONOGESTREL, PRODUCTSYNONYM: NUVARING - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	10 Feb 2021 15:53:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Feb 2021 15:53:48
Data point term sent to Coder	System	10 Feb 2021 15:53:08
User entered 'NUVA RING'	(b) (4), (b) (6)	10 Feb 2021 15:52:58

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:12:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:52:58

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:12:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'BIRTH CONTROL'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:52:58

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:12:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered '1'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:52:58

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:12:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:52:58

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:12:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'UNIT'	(b) (4), (b) (6)	10 Feb 2021 15:52:58

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:12:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'every month (QM)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:52:58

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:12:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:52:58

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:12:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:52:58

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:12:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'INTRAVAGINAL'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:52:58

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:12:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	10 Feb 2021 15:53:11
User entered '21 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 15:53:11
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	10 Feb 2021 15:52:58
User entered '21 Dec 2021'	(b) (4), (b) (6)	10 Feb 2021 15:52:58

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:12:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:52:58

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:12:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:52:58

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:12:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:52:58

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:12:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:52:58

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:12:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Feb 2021 15:52:58

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:12:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Feb 2021 15:52:58

US3312587

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:12:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '802 (802)'	System	10 Feb 2021 15:52:58

US3312587

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:12:54

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:26:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:08:22
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
User entered 'Yes (Y)'	(b) (4)	24 Nov 2020 14:47:27
	Karol Moore (b) (4)	
	(b) (4)	

US3312587

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:12:54

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered '23 Oct 2020'	Karol Moore (b) (4)	24 Nov 2020 14:47:48
	(b) (4)	

US3312587

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:12:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'tuberculosis skin test'	Karol Moore (b) (4)	24 Nov 2020 14:47:48
	(b) (4)	

US3312587

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:12:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered 'Diagnostic (DIAGNOSTIC)'	Karol Moore (b) (4)	24 Nov 2020 14:47:48
	(b) (4)	

US3312587

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:12:54

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:13:38
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	24 Nov 2020 14:47:48
	(b) (4)	

US3312587

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:12:54

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:00:30
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:57:16

US3312587

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:12:54

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:00:30
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'Due to SARS-COV-2 (COVID)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:57:16

US3312587

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:12:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:00:30
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:57:16

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
Un-reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 15:32:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 15:32:29
User entered 'USA-US300-2020-MRNA-1273-P301000004'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'No (N)'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'No (N)'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'No (N)'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'No (N)'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'No (N)'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'No (N)'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'No (N)'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'Carlos'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'Fierro'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered '16300 College Blvd'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'Shawnee'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'KS'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered '66219'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 21:33:42
User entered 'US'	System	13 Oct 2020 15:32:41

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	19 Nov 2020 19:43:41
User entered '3'	System	11 Nov 2020 21:23:27
User entered '2'	System	22 Oct 2020 21:33:54
User entered '1'	System	13 Oct 2020 15:32:41

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
Un-reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 15:32:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 15:32:29
User entered 'USA-US300-2020-MRNA-1273-P301000004'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'No (N)'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'No (N)'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'No (N)'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'No (N)'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'No (N)'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'No (N)'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'No (N)'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'Carlos'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'Fierro'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered '16300 College Blvd'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'Shawnee'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'KS'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered '66219'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 21:33:42
User entered 'US'	System	13 Oct 2020 15:32:41

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	19 Nov 2020 19:43:41
User entered '3'	System	11 Nov 2020 21:23:27
User entered '2'	System	22 Oct 2020 21:33:54
User entered '1'	System	13 Oct 2020 15:32:41

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:12:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '13/Oct/2020 15:32'	(b) (4) System	13 Oct 2020 15:32:41

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:12:54

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 21:33:42
User entered 'I'	(b) (4), (b) (6)	13 Oct 2020 15:32:41

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
Un-reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 15:32:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 15:32:29
User entered 'USA-US300-2020-MRNA-1273-P301000004'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'No (N)'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'No (N)'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'No (N)'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'No (N)'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'No (N)'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'No (N)'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'No (N)'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'Carlos'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'Fierro'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered '16300 College Blvd'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'Shawnee'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'KS'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered '66219'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 21:33:42
User entered 'US'	System	13 Oct 2020 15:32:41

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	19 Nov 2020 19:43:41
User entered '3'	System	11 Nov 2020 21:23:27
User entered '2'	System	22 Oct 2020 21:33:54
User entered '1'	System	13 Oct 2020 15:32:41

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:12:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '22/Oct/2020 21:33'	(b) (4) System	22 Oct 2020 21:33:54

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:12:54

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 21:33:58
User entered 'I'	(b) (4), (b) (6)	22 Oct 2020 21:33:54

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
Un-reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 15:32:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 15:32:29
User entered 'USA-US300-2020-MRNA-1273-P301000004'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'No (N)'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'No (N)'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'No (N)'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'No (N)'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'No (N)'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'No (N)'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'No (N)'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'Carlos'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'Fierro'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered '16300 College Blvd'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'Shawnee'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'KS'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered '66219'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 21:33:42
User entered 'US'	System	13 Oct 2020 15:32:41

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	19 Nov 2020 19:43:41
User entered '3'	System	11 Nov 2020 21:23:27
User entered '2'	System	22 Oct 2020 21:33:54
User entered '1'	System	13 Oct 2020 15:32:41

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:12:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '11/Nov/2020 21:23'	(b) (4) System	11 Nov 2020 21:23:27

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:12:54

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:43:31
User entered 'I'	(b) (4), (b) (6)	11 Nov 2020 21:23:27

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
Un-reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 15:32:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 15:32:29
User entered 'USA-US300-2020-MRNA-1273-P301000004'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'No (N)'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'No (N)'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'No (N)'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'No (N)'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'No (N)'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'No (N)'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'No (N)'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'Carlos'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'Fierro'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered '16300 College Blvd'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'Shawnee'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered 'KS'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:32:34
User entered '66219'	System	13 Oct 2020 15:32:11

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 21:33:42
User entered 'US'	System	13 Oct 2020 15:32:41

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:12:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	19 Nov 2020 19:43:41
User entered '3'	System	11 Nov 2020 21:23:27
User entered '2'	System	22 Oct 2020 21:33:54
User entered '1'	System	13 Oct 2020 15:32:41

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:12:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered '19/Nov/2020 19:43'	(b) (4) System	19 Nov 2020 19:43:41

US3312587

Folder: SAE USA-US300-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:12:54

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:14:01
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:43:41